“COMPARATIVE STUDY OF MID EXPIRATORY FLOW RATE BY USING SPIROMETRY IN ASYMPTOMATIC SMOKERS AND NON SMOKERS AS A MARKER OF EARLY AIRFLOW OBSTRUCTION”

A Dissertation Submitted to

THE TAMILNADU DR. M.G.R MEDICAL UNIVERSITY

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In Partial Fulfillment of the Regulations

For the Award of the Degree of

M.D. (GENERAL MEDICINE) - BRANCH – I

GOVERNMENT KILPAUK MEDICAL COLLEGE
CHENNAI

MAY 2019

BONAFIDE CERTIFICATE

This is to certify that "**COMPARATIVE STUDY OF MID EXPIRATORY FLOW RATE BY USING SPIROMETRY IN AYMPTOMATIC SMOKERS AND NON SMOKERS AS A MARKER OF EARLY AIRFLOW OBSTRUCTION".** is a bonafide work done by **Dr. PAVITHRA .P.** Post graduate student, Department of General Medicine, Kilpauk Medical College, Chennai-10, under my guidance and supervision in partial fulfillment of rules and regulations of the TamilNadu Dr. M.G.R Medical University, for the award of M.D. Degree Branch I (General Medicine) during the academic period from MAY 2016 To MAY 2019.

PROF. DR. K.V. RAJALAKSHMI M.D.
Guide for the study,
Professor and Head of the Department,
Department of Medicine,
Govt. Kilpauk Medical College,
Chennai.

PROF. DR P. VASANTHAMANI ,
M. D., D.G.O., MNAMS.,DCPSY.,MBA
DEAN
Govt. Kilpauk Medical College
Chennai -600010

DECLARATION

I solemnly declare that this dissertation "**COMPARATIVE STUDY OF MID EXPIRATORY FLOW RATE BY USING SPIROMETRY IN ASYMPTOMATIC SMOKERS AND NON SMOKERS AS A MARKER OF EARLY AIRFLOW OBSTRUCTION"** was prepared by me at Government Kilpauk Medical College and Hospital, Chennai, under the guidance and supervision of **Prof. Dr. K. V. RAJALAKSHMI M.D.,** Professor and Head of the Department, Department of Internal Medicine, Government Kilpauk Medical College and Hospital, Chennai. This dissertation is submitted to **The Tamil Nadu Dr. M.G.R. Medical University, Chennai** in partial fulfillment of the University regulations for the award of the degree of **M.D. Branch I (General Medicine)**.

CERTIFICATE BY THE GUIDE

This is to certify that the dissertation titled "**COMPARATIVE STUDY OF MID EXPIRATORY FLOW RATE BY USING SPIROMETRY IN AYMPTOMATIC SMOKERS AND NON SMOKERS AS A MARKER OF EARLY AIRFLOW OBSTRUCTION".** in the General Surgery Department at Govt. Kilpauk Medical College Hospitalis a bonafide research work done by **Dr. P. PAVITHRA,** Post Graduate in M.D. General Medicine, Government Kilpauk Medical College & Hospital, Chennai-10 under my direct guidance and supervision in my satisfaction and in partial fulfillment of the requirements for the degree of **M.D. General Medicine**

Prof. Dr. K.V. RAJALAKSHMI M.D.
Guide for the study,
Professor and Head of the Department,
Department of Medicine,
Govt. Kilpauk Medical College,
Chennai.

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INSTITUTIONAL ETHICS COMMITTEE
GOVT. KILPAUK MEDICAL COLLEGE,
CHENNAI-10
Protocol ID. No. 65/2018 Meeting held on 13.02.2018

The Institutional Ethical Committee of Govt. Kilpauk Medical College, Chennai reviewed and discussed the application for approval "***COMPARATIVE STUDY OF MID EXPIRATORY FLOW RATE USING SPIROMETRY IN ASYMPTOMATIC SMOKERS AND NON SMOKERS AS A MARKER OF EARLY AIRFLOW OBSTRUCTION***" submitted by Dr.P.Pavithra, Post Graduate in General Medicine, Govt. Kilpauk Medical College, Chennai-10.

The Proposal is **APPROVED.**

The Institutional Ethical Committee expects to be informed about the progress of the study any Adverse Drug Reaction Occurring in the Course of the study any change in the protocol and patient information /informed consent and asks to be provided a copy of the final report.

26.2.2018
DEAN
Govt. Kilpauk Medical College,
Chennai-10.

26-2-18

ME 1 Sec> Ethical Committee

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At the outset, I would like to thank my beloved Dean, Kilpauk Medical College, **PROF. Dr P. VASANTHAMANI, M. D., D.G.O., MNAMS., DCPSY., MBA.** for her kind permission to conduct the study in Kilpauk Medical College.

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I would always remember with extreme sense of thankfulness for the valuable time, co-operation , criticism and support provided by my fellow post graduates, juniors , C.R.R.I's and friends.

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I would like to take this opportunity to show gratitude to my friends & family for their never ending support in completing this thesis.

Finally, I wholeheartedly thank all my patients for their active cooperation in this study, without whom this would not have become a reality.

LIST OF ABBREVIATIONS

COPD	-	Chronic obstructive lung disease.
WHO	-	World Health Organization.
NFHS	-	National Family Health Survey.
GDP	-	Gross domestic product.
LMIC	-	Low- and Middle-Income countries.
NCD	-	Non-Communicable Diseases.
FCTC	-	Framework Convention on Tobacco Control.
MHFW	-	Ministry of Health and Family Welfare.
GOI	-	Government of India.
NSSO	-	National sample survey organization.
CCEF	-	Christian Counselling and Educational Foundation.
IEC	-	Information education and communication.
PHFI	-	Public Health Foundation of India.
GATS	-	Global Adult Tobacco Survey.
NNK	-	4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone.

PAH	-	Polycyclic aromatic hydrocarbons.
DNA	-	Deoxy ribonucleic Acid.
FEV1	-	Forced Expiratory volume at 1 second.
EAG	-	Empowered Action Group.
ICMR	-	Indian Council of Medical Research.
IHME	-	Institute for Health Metrics and Evaluation.
DALY	-	Disability adjusted life years.
LFQ	-	Lung function questionnaire
DLCO	-	Diffusing capacity of lung for carbon monoxide

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INTRODUCTION

Smoking is a major addiction in this era and even with widespread criticism, its use is on the rise. Smoking dates back to 5000 BC and it has taken many forms. As civilization evolves in many parts of the world the form of smoking gets a various shape. Currently, the major form of smoking is cigarette smoking with tobacco as its content. Ill effects of smoking have been publicized widely for the last 60 -70 years by governments all over the world. These steps have prevented a surge in tobacco smoking but nevertheless to say its use is on a plateau with many youngsters at risk to its use. Growing urban settlements, peer pressure, and rising social miscreants are some of the causes targeting the younger generation to lure them into various addictions with cigarette smoking as the initial step. Cigarettes are easily available than other substance abuse products. Hence cigarette smoking in the long-term has caused a major burden on the economy globally. Health-related issues are on raise. Cigarette smoking has been one of the attributes to a large number of respiratory ailments and cancer.

There is no respiratory pathology without cigarette smoking as its cause. That’s the nature of its ill effects caused by cigarette smoking. A multitude of cancer has its etiology or a trigger as smoking. Many non-communicable diseases like hypertension, reproductive diseases among men and women have been linked to smoking. Various Governments and health agencies are crying out to the public to curb its use in ways it may reach a large section of the population. Our Indian government and various state administrations have taken various actions. Ban commercial advertisements for cigarettes, portray

the oncogenic and respiratory ailments on packets and to limit the use of cigarette smoking by actors on Television and movie platforms with statutory warnings. The ban on non-smokable tobacco has made cigarette as a sole recreational product available to people with its addiction. Hence, cigarette smoking is something that is hugely popular, and its containment is very difficult among the general public. We are trying to bring the ill-effects of cigarettes at a prevention level.

In this study, we have elaborated its ill effects by comparing to non-smokers.Chronic obstructive pulmonary disease (COPD) is one such respiratory ailment which is on rising to cause mortality and morbidity and resulting in a huge burden on the health care system and economic productivity socially [1]. COPD is an anatomical damage caused to lungs by the direct effects of smoking.COPD on a larger scale has no connections with genetic and other individual parameters among smokers. It depends on the number of cigarettes smoked per day and years with smoking history.

More the exposure to harmful toxins more the damage to the fragile lung parenchyma and its conduits. An obstructive pattern can be identified early with Pulmonary function tests. One such parameter is Mid-expiratory flow rate (MEFR) which identifies the obstruction of the smaller airways like bronchioles at earliest[2]. Importance of this particular parameter lies its ability to detect the obstruction of airways which can be reversed with complete abstinence from smoking. We take asymptomatic smokers and comparable non-smokers into the study and analyze the MEFR.

AIMS AND OBJECTIVES

The aims and objectives of my study includes:

1. To study the influence of smoking on pulmonary functions
2. To study the differences in Mid Expiratory Flow Rate values in smokers and non-smokers and their variation.
3. To study the ventilatory impairment caused by smoking in terms of obstructive, restrictive or mixed type.
4. To establish normal standards in healthy non-smoker adults.
5. To use pulmonary function test as a tool to identify the quantum of damage to the respiratory tree.
6. To create awareness about the ill effects of smoking.

REVIEW OF LITERATURE

Smoking:

Cigarette smoking referred to just smoking in this work is the major preventable cause of non-communicable ailments which impair the economic productivity and health of major economies around the world. More alarming is the rising trend in smoking among the adolescents and its worrying spread within communities in the developing world [3]. Smoking is an important risk factor for Non-communicable diseases. Total burden of NCD is expected rise from 40% in 1990 to 75% in 2030 [11]. Analyzing the reliable predictors of smoking onset help in developing effective programs in preventing smoking. These parameters include socioeconomic status, peer pressure, knowledge in-terms of literacy, attitude, family background, and support. Smoking onset involves various factors and its maintenance ranges from trying, experimenting and a regular smoker. Lower socioeconomic status, single parent, school, and the area where it is located, money availability are some of the factors luring adults into smoking.

Social bonding which includes family bonding, peer bonding, school influences, and religion. Family bonding in terms of attachment to father/ mother, level of supervision, strictness is considered. Single parent status and inappropriate emotional connect with teens are major risk factors in the ignition of smoking. Family smoking in terms of father/sibling smoking has good predictive value. Of more important was sibling smoking habit which has

higher predictive value. Peer pressure in terms of bonding with groups who smoke and who don't smoke. As expected peer groups who smoke are at higher risk. School influences many habits like alcohol and smoking. Academic grades, achievements, extracurricular activities play a decisive role in smoking initiation.

Six domains of determinant of tobacco use includes social environment, socialbonding, sociallearning, pharmacologic effects, intra-psychic skills and Knowledge - attitude - behavior (KAB) principles.

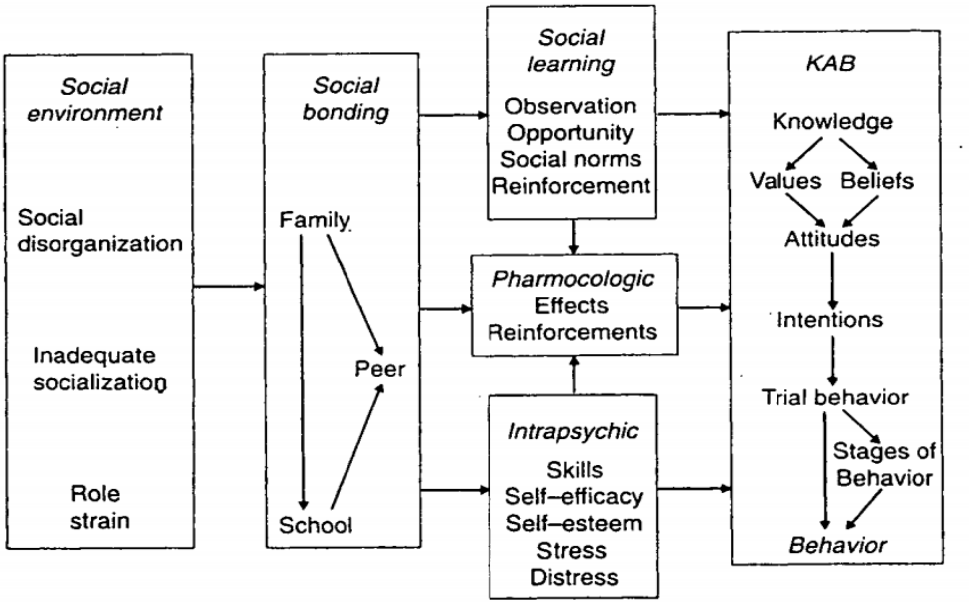


Figure-1: Six domains of determinants of tobacco use

Tobacco kills around six million people every year globally. WHO estimates around 10 crore people died prematurely due to tobacco-related diseases in the 20th century. This figure may rise to 100 crores if not addressed seriously by health agencies around the world [4].

In the 1980s tobacco deaths were around 630000 per year [5]. Current estimates have increased to 800000 to 900000 per year and there are no signs of decline. Among the attributes, an alarming one is the incidence of oral cancers among men and women. Easy availability of different smoking and non-smoking forms of tobacco lead to cancers especially mouth cancer. Heart-related ailments in people less than 40 years is contributed by smoking. Every year 4.5 million smokers in India suffer from heart ailments and 3.9 million people from respiratory diseases. Noteworthy is that these morbidities are completely preventable. World Health Organization (WHO) predicts the number of deaths related to smoking may increase to 1.5 million by 2020 [6]. In a study conducted by Gupta et al shows around 23.7% of the deaths among men and 23.7% of the deaths among women in the economically productive age group are due to tobacco-related illness [7].

In our country NFHS -3 surveys (National Family Health Survey - 3) conveyed that smoking is more prevalent among men, rural population, the illiterate, poor and vulnerable section of the society [8].In India's smoking pattern is a complex problem as there are many products and its cultural beliefs give rise to many deep-rooted menaces in bringing down its use. People smoke beedis which are manufactured at cottage-based enterprises and cigarettes from multinational companies. Beedis are largely consumed than cigars,[12] especially among the rural population and low socioeconomic state people. According to Pednekar et al. beedi smokers have a higher incidence of oral cancers than cigarette smokers [11]. India is a low and middle-income country; LMIC.With its

limited expenditure on health-related services which is around 1.15% of GDP[9,10]. National sample survey organization (NSSO)has done an extensive report on smoking in all the states and have predicted the surge in its use in coming years. With such a rise in smoking-related health issues and limited resource allocation to the health sector need for early intervention by educating the people on scientific basis is of paramount importance.

States-region	2,015		2,020		2025	
	Urban	Rural	Urban	Rural	Urban	Rural
A&N Island	73952	102946	88938	106856	111417	100666
Andhra Pradesh	1080469	2794191	1129354	2890592	1326044	2812667
Arunachal Pradesh	110004	185845	102438	129021	80614	77620
Assam	2236113	11871681	2536139	12357793	2926348	12626584
Bihar	6904750	58580736	7304425	61776223	8120986	63961367
Chandigarh	92084	10437	113733	12823	138961	9423
Chattisgarh	2047064	6353887	2316631	6581046	2752540	6570198
D&N Haveli	42981	29353	61851	23063	75304	18520
Daman & Diue	1737	5807	1809	7497	2237	8306
Delhi	1219530	49149	1415330	46143	1644141	28716
Goa	18120	11175	21510	11040	25650	8850
Gujarat	1392660	1959714	1524150	2014578	1852632	1853442
Haryana	549436	992984	630661	1021293	772605	979199
Himanchal Pradesh	36382	277750	40087	286276	44819	291633
Jammu & Kashmir	122260	319898	133162	330548	157377	323064
Jharkhand	4894785	15742872	5320554	16606840	6305105	16721207
Karnataka	1738536	2776353	1890574	2815221	2262522	2598963
Kerala	242946	714825	247320	735750	285444	717120
Lakshadweep	4641	11300	4237	12914	4641	11703
Madhya Pradesh	5298396	13504222	4275745	10565318	3327574	6783870
Maharashtra	15817919	17282516	15024244	15191775	15355689	11308761
Manipur	67612	199811	70012	211497	82637	211289
Meghalaya	188243	705097	203224	737014	237421	744179
Mizoram	90922	75557	98683	76507	118642	64310
Nagaland	28311	135433	29911	142389	34293	145589
Orissa	1111880	5234103	1219559	5370998	1393954	5399914
Pondicherry	4529	1942	5504	2233	6997	1835
Punjab	974478	1430124	1078595	1430624	1292830	1304167
Rajasthan	2605830	8200196	2809570	8715026	3341065	8796402
Sikkim	31862	187402	36658	193912	42482	198708
Tamil Nadu	2087219	1478871	2315969	1332105	2664106	1039709
Tripura	280049	1134779	371021	1409433	504005	1659212
Uttarakhand	291673	697753	324280	724517	389211	709156
Uttar Pradesh	9699598	33554776	8123367	27145097	6588320	18848253
West Bengal	2364562	5878690	2486533	6104141	2940279	5948655
India	63751534	192492178	63355778	187118102	67208891	172883259

Due to the globalization of the tobacco epidemic WHO framework convention on tobacco control (WHO FCTC) was formed with the aim of reducing the burden of the disease. It was adopted in May 2003 and India was the eight country to pursue its ideas. Various guidelines were proposed to encourage smokers to quit smoking and more importantly restrain non-smokers from taking up such habits. Global political will for tobacco control is appreciated by the fact that more than 86% of the world's population is under the FCTC guidelines. This makes WHO FCTC more comprehensive and successful.

Since 1975, there is a mandatory display of a statutory warning on the cigarette and other tobacco products. Through Cigarettes and other tobacco products Act (COTPA) certain rules were formulated and it was reinforced from 1 May 2004.

The key provisions of COTPA -2003 [12] are as follows:

- Prohibition of smoking in public places (including indoor workplaces). Its implementation starts from 2nd October 2008.

- Prohibition of advertisement, direct and indirect (point-of-sale advertising is permitted), sponsorship and promotion of tobacco products.

- Prohibition of sales to minors (tobacco products cannot be sold to children less than 18 years of age and cannot be sold within a radius of 100 yards of any educational institutions).

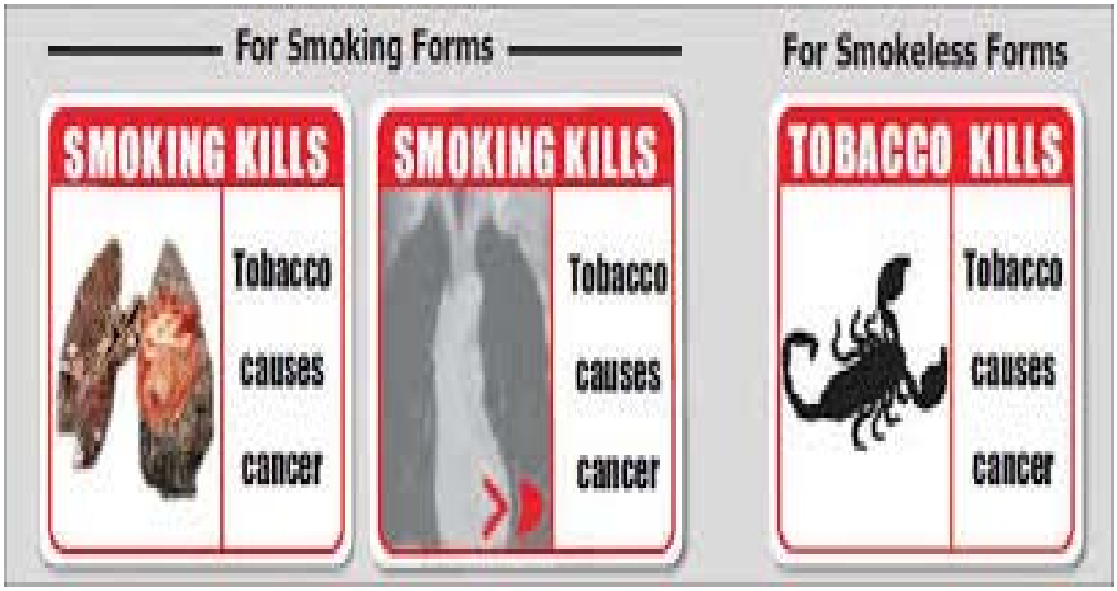
- Regulation of health warning in tobacco products packs. Health warnings are typed in English and in the local Indian language. Pictorial health warnings also to be included.

- Regulation and testing of tar and nicotine contents of tobacco products and declaring on tobacco products packages.

National Tobacco Control Programme (NTCP):

The government of India (GOI)through Ministry of Health and Family Welfare (MHFW) launched NTCP in the eleventh 5-year plan to bring about greater awareness at local levels and to involve grass root workers in health care settings for tobacco control. It strengthens the WHO-FCTC guidelines. It was approved by the Cabinet Committee on Economic Affairs (CCEA) on 28

January 2010. Information, Education, and Communication (IEC) activities at district levels are held at regular intervals with the help of NGOs, Police personnel, education and local bodies. These activities are carried by the Headquarters at the regional level in all districts. The web portal has been created for training and research activities related to tobacco control. The public health foundation of India (PHFI) launched this initiative [13]. Tobacco surveillance has been included in the integrated disease surveillance programme and hence awareness level increases at all levels.



Prototype board for tobacco free zone: A board shall be displayed prominently at each entrance of the building, near the lift and on different wings one each floor.


THIS PREMISE/BUILDING IS TOBACCO FREE
Use of any form of tobacco in this premise is prohibited and is a punishable offence with fine up to Rs. 200/-
If you find anybody smoking/spitting tobacco please report to:
Name:.....
Designation: ..... Telephone No:.....
NATIONAL HEALTH MISSION
To quit tobacco call 1800 11 2356 or give a missed call at 011-22901701


This Premise / Building is Tobacco Free
You are entering into the Tobacco Free Zone
Taking tobacco products inside the Premise / Building is prohibited
NATIONAL HEALTH MISSION
National Tobacco Control Programme
Ministry of Health and Family Welfare

Global adult Tobacco survey -2 (GATS-2) Fact sheet INDIA 2016-2017:

It is a household survey of persons aged 15 and above conducted in all states and union territories. The first round was conducted in 2009-10 [14]. The second round in 2016-17 by Tata Institute of social sciences, Mumbai. A total of 74,037 individuals were interviewed from August 2016 to February 2017.

Objectives of GATS is to systematically monitor adult tobacco use and track key tobacco control indicators. It helps countries like India to fulfill their obligations under the WHO FCTC and to generate data within and across countries.

Key findings in GATS 2 include the following:

- Prevalence of tobacco use has been decreased by 6 percentage from 34.6% in GATS-1 in 2009-10 to 28.6% in 2016-17.
- 19.0% of men, 2.0% of women and 10.7% of all adults' smoke tobacco.
- Khaini and bidi are the most commonly used products.11% use khaini and 8% use bidi.
- Prevalence of tobacco use among minors aged 15-17 has been decreased from 10% in GATS-1 to 4% in GATS-2.
- 55% of smokers are planning or thinking to quit smoking.49 % of smokers were advised by health care providers to quit tobacco.

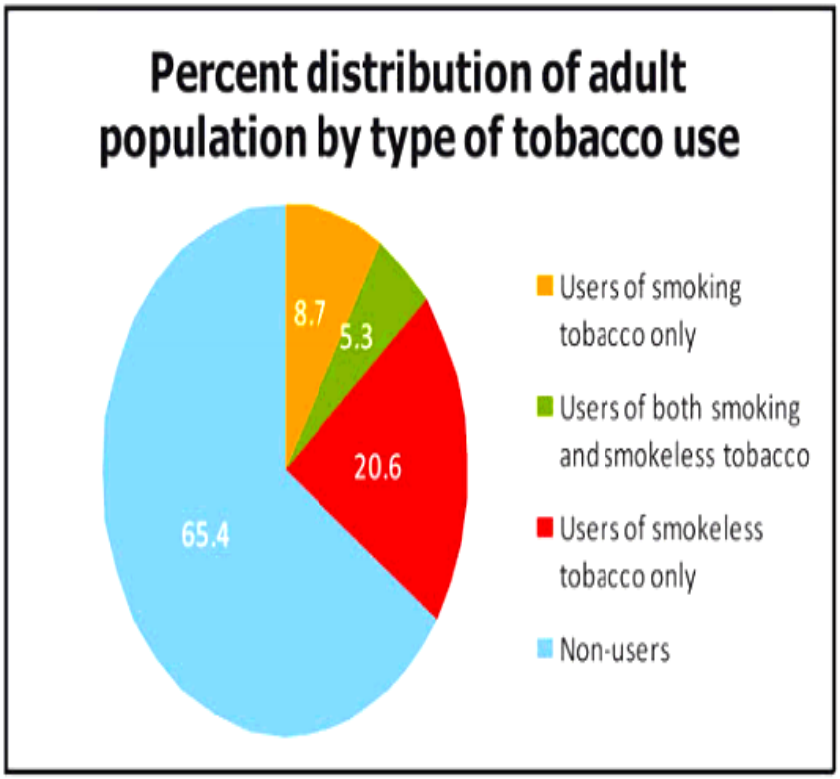
- 3 in every 10 adults who work indoors are exposed to second-hand smoke at their workplace.

- 13% of smokers noticed smoking tobacco advertisement and 75% smokers noticed information about the dangers of smoking tobacco or that encourages quitting on television or radio.

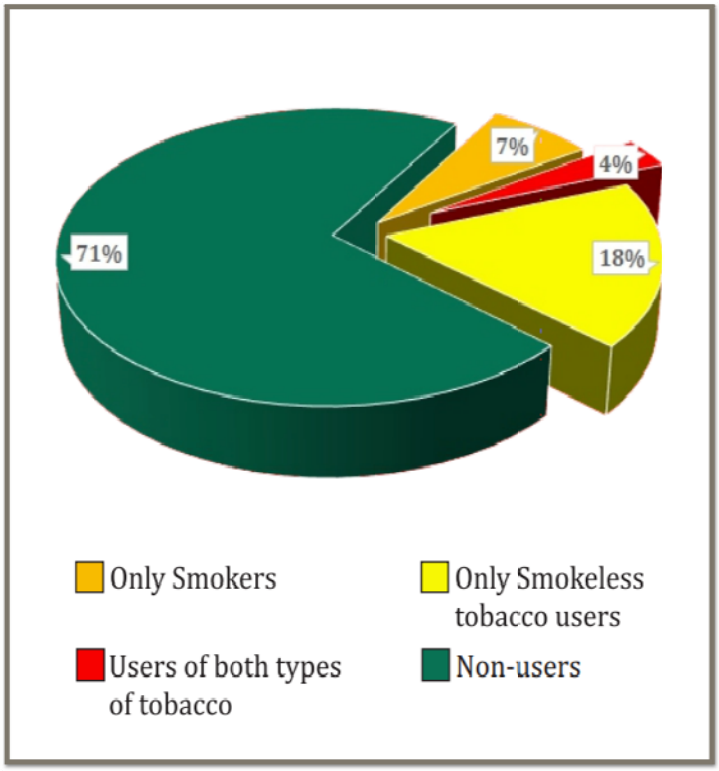
- 62% of cigarette and 54% of bidi smokers thought of quitting because of warning label on packets,

- 92% of adults believe smoking causes serious illness.

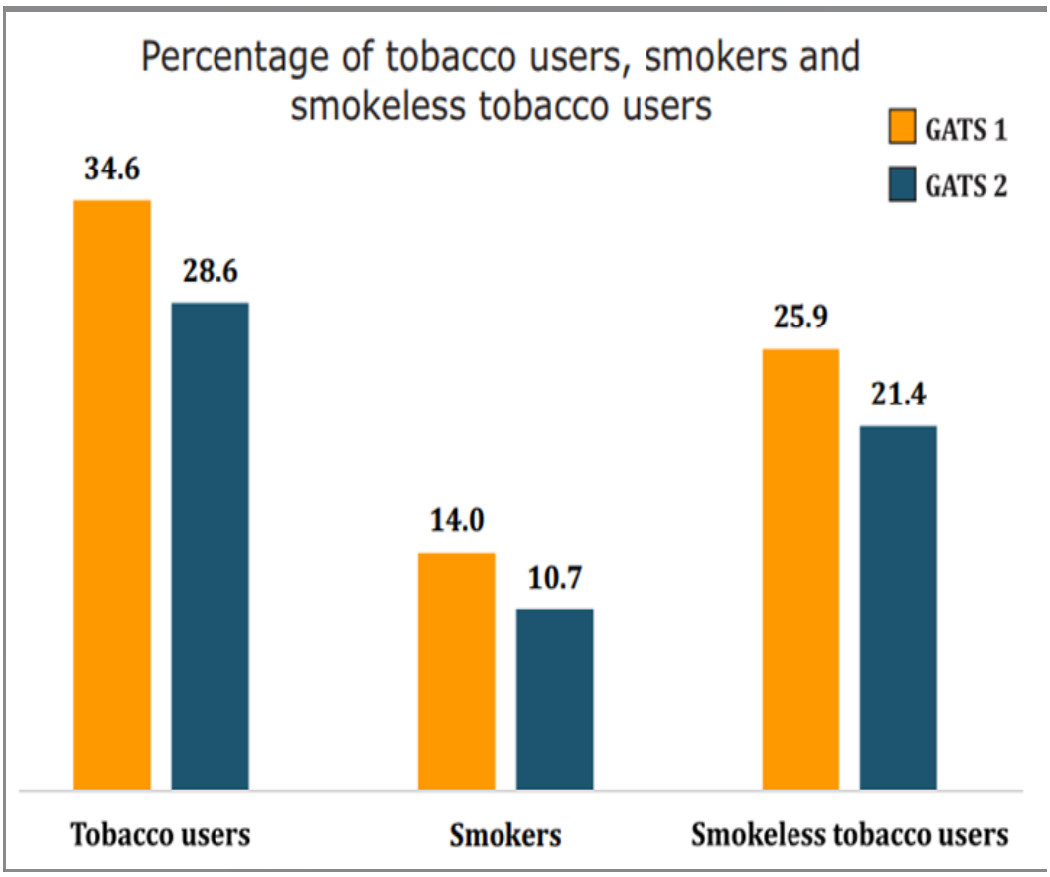
Certain important findings from GATS-2:

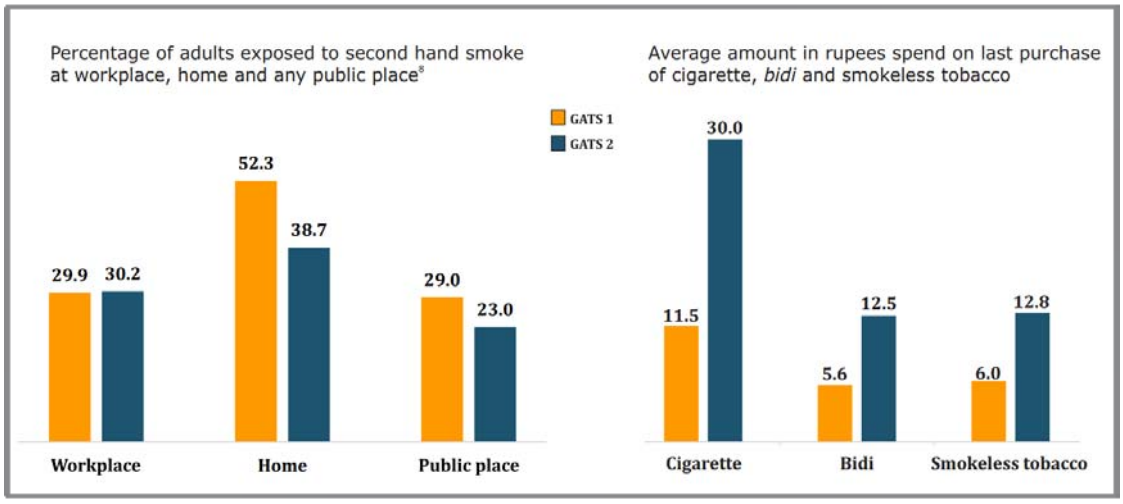


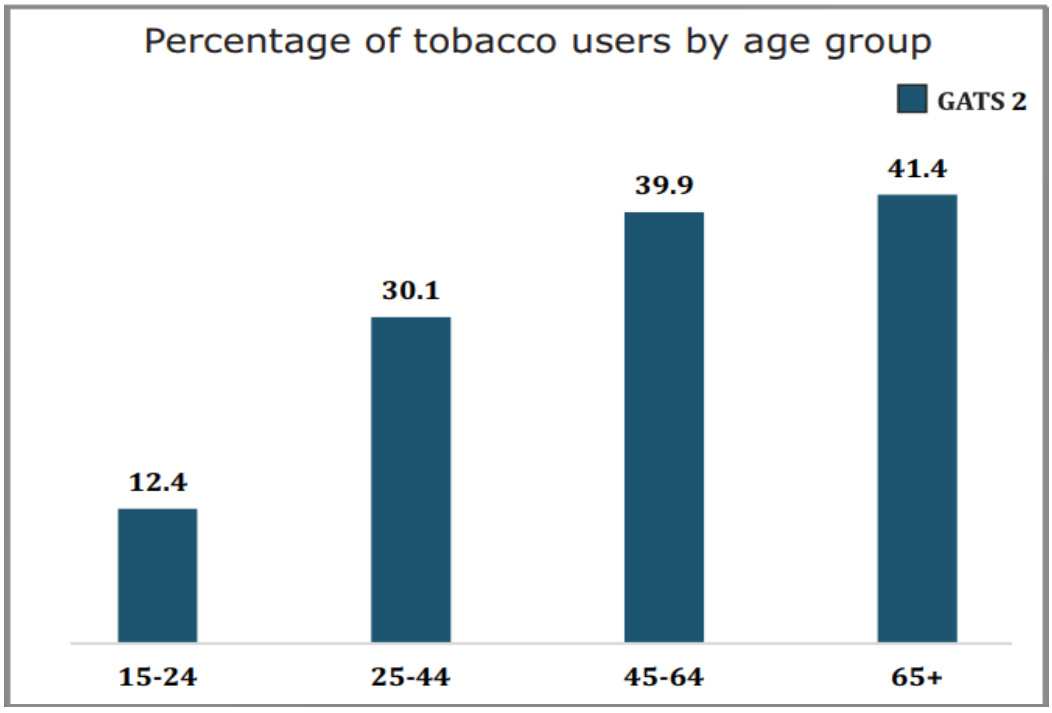
GATS-1 (2009-10)

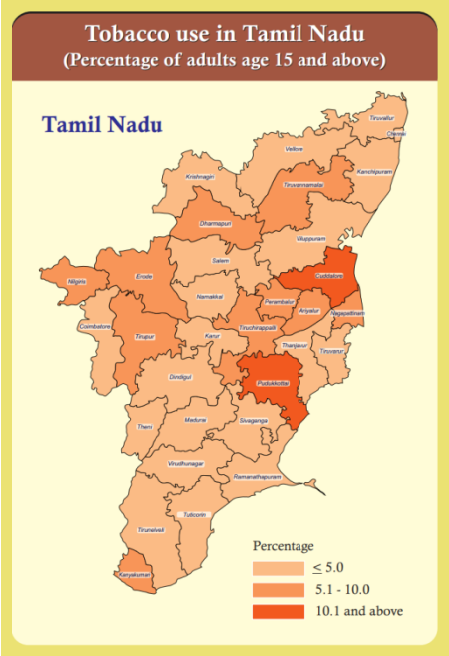


GATS-2 (2016-17)




Percentage of adults exposed to second hand smoke at workplace, home and any public place
GATS 1
GATS 2
29.9
30.2
52.3
38.7
29.0
23.0
Workplace
Home
Public place
Average amount in rupees spend on last purchase of cigarette, bidi and smokeless tobacco
11.5
30.0
5.6
12.5
6.0
12.8
Cigarette
Bidi
Smokeless tobacco


Percentage of tobacco users by age group
GATS 2
12.4
30.1
39.9
41.4
15-24
25-44
45-64
65+



Tamil Nadu Tobacco Survey (TNTS) ; 2015-16

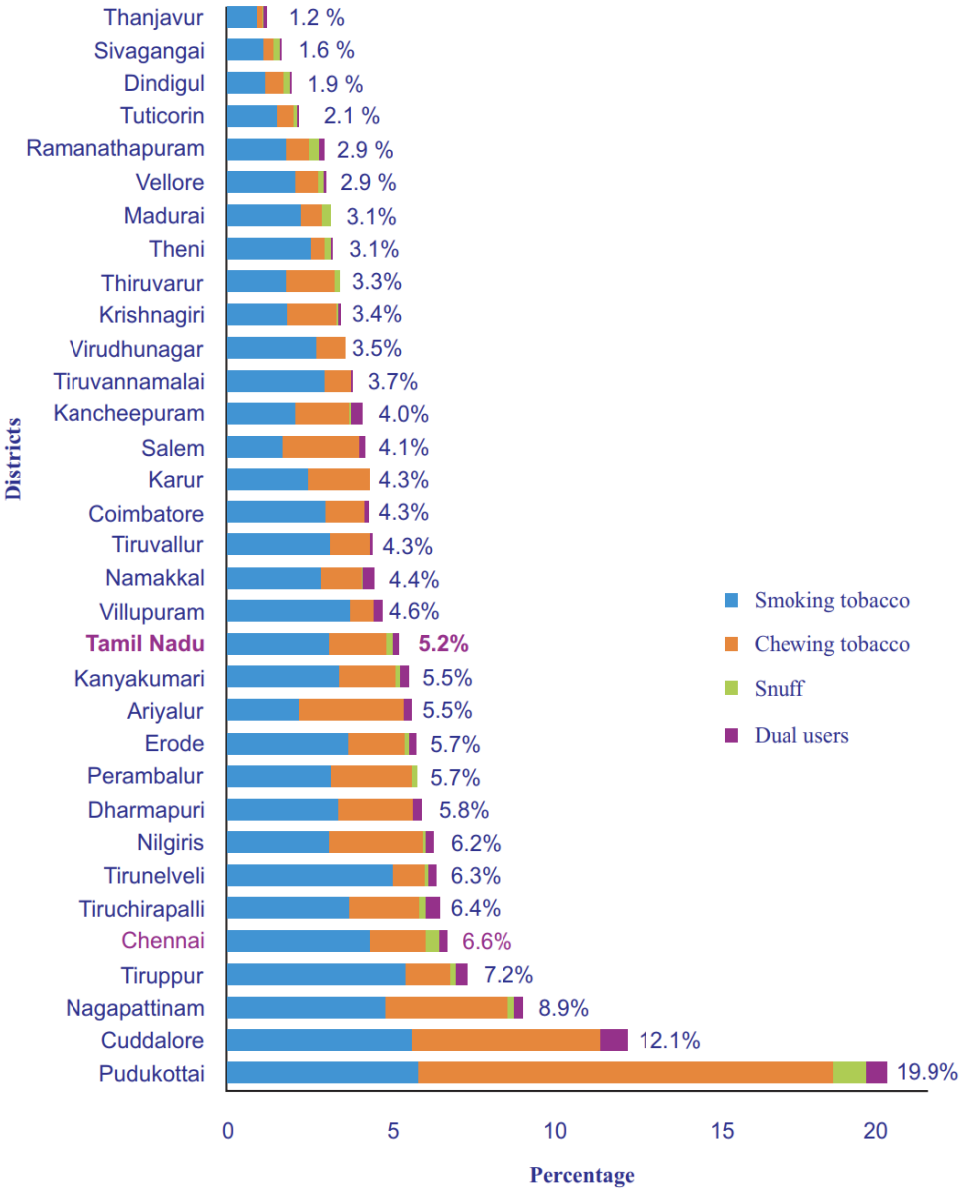
TNTS is a large statewide population-based survey conducted in all the 32 districts of Tamil Nadu, representing both rural and urban population. The survey interviewed about 100, 000 individuals aged 15 years and above. The aim of the survey was to systematically monitor the tobacco use (in any form) and track the key outcome indicators for tobacco control based on WHO's MPOWER guidelines. TNTS will assist the state of Tamil Nadu in fulfilling the obligations of the Framework Convention on Tobacco Control (FCTC) by developing appropriate tobacco control policies at the district level and allocating resources accordingly. The data generated can be helpful in making comparisons across and within districts.

111,363 individuals were identified from 32945 households.99825 individuals completed the requisite process in the interview. The overall Household response rate was 89.24%. GATS questionnaire was translated into Tamil.31 educational institutes and 3 NGO's participated in the survey.

Things that were assessed include:

- Prevalence of tobacco use
- Exposure to second-hand smoke
- Cessation of smoking
- Impact of tobacco control measures.
- Prevention initiatives in TamilNadu

TOBACCO USE IN TAMIL NADU



Regarding tobacco use:

1. An estimated 28, 64, 400 people aged 15 years & above in Tamil Nadu, use tobacco in any form.

2. The overall prevalence of tobacco use in Tamil Nadu was 5.2%.

3. Tobacco use among males was higher (4.3%) compared to females (0.9%).

4. Smoking tobacco-3.3% (Cigarette users - 1.7%, Bidi users - 1.4%) Smokeless tobacco - 2.1%.

5. The highest prevalence rate was observed in Pudukkottai District (19.9%) and the lowest was in Thanjavur district (1.2%).

6. No differences in tobacco use between urban (2.5%) and rural areas (2.6%) of Tamil Nadu.

7. Tobacco use prevalence had come down from 16% in the year 2009-2010 (Global Adult Tobacco Survey: 2009-2010) to 5.2% in the year 2015-2016 in Tamil Nadu.

8. Average age at initiation of tobacco use was 24.7 years; 25.7% of the respondents initiated the use before the age of 18 years.

9. 47% of current tobacco users consumed tobacco within half an hour of waking up.

Cessation:

1. 54% of the current users were concerned about their tobacco use
2. 17.2% of the current users reported that they were thinking of quitting in the next one month
3. 38.9% of the current users had tried to quit tobacco in the last 12 months Cessation methodologies used were counseling (14.3%), NRT & Medication (3.4%), Self-attempt (7.1%)
4. 34.9% current users were asked for their tobacco use by a healthcare provider in the last 12 months
5. 37.7% of the current users were advised by a health care provider to quit tobacco

Pictorial warnings:

Survey were conducted regarding pictorial warning and its impact on smoking cessation:

1. 67.3% of the current tobacco users noticed pictorial warning on the tobacco products they used, in the last one month.
   Smokers-63.6%, (Cigarettes-38.5%, Bidi-25.2%), Smokeless tobacco users-32%, Dual users-4.3%

2. Of the current tobacco users who noticed pictorial warning, 61.3% were motivated to quit.

Smokers-64.2%, (Cigarettes-37.4%, Bidi-26.8%), Smokeless tobacco users-29.7%, Dual users-3.6%

Smoke free Policies at home and work place:

1. 96.6% of the respondents reported that smoking is not permitted at their home, however 15% of the houses had people smoking at home, daily.
2. 15.7% of the respondents reported that their workplace did not have any smoke free policy and in 5.7% of the workplaces, smoking was allowed everywhere.

Role of Media:

1. Respondents who noticed anti-tobacco messages in the last one month: 91.9% Television - 7 7. 1 %,Newspaper - 1 4. 6 %, Films-23.3%, Theatre - 16%
2. 78.4% of the respondents noticed tobacco advertisement or promotional messages in the last one month. Television 12.2 %, News Paper 2.9 %, Films 3.4 %, Theater 2.7%

Knowledge Attitude and Perception:

1. 95% of the respondents were aware that tobacco causes serious illness.
2. 70.6% of the respondents believed exposure to tobacco smoke causes serious illness among non-smokers.
3. Respondents attributed tobacco use with Cancer - 80%, Heart attack – 33.5%, Infertility- 4.6%.

Smoking and nicotine:

Nicotine is the primary compound responsible for the ill effects of smoking. It is involved in psychological and pharmacological mechanisms responsible for addiction and maintenance. It activates the dopaminergic system[15,16] in the mesolimbic pathway and it is responsible for the withdrawal effects of smoking cessation. Nicotine acts at neuronal acetylcholine receptors throughout the central nervous system and at the level of postsynaptic junction in the autonomic nervous system.

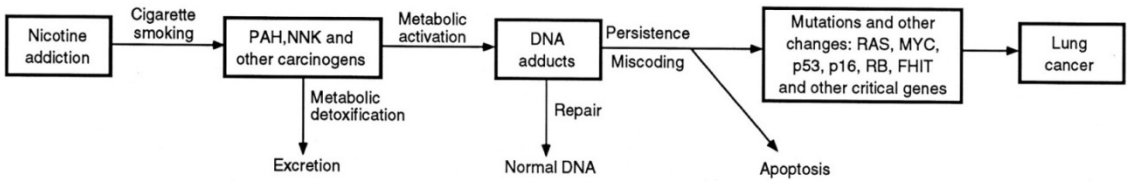
A gradual increase in these receptors with daily nicotine use explains its tolerance. Hence, smokers of cigarettes increase the smoking rate, intensity to maintain the nicotine levels in plasma[17]. Studies show smokers extract around 1-2 mg of nicotine per cigarette whereas the amount measured by smoking machines using human parameters is around 2-3 mg per cigarette. This shows smokers absorb half of the nicotine inhaled [18]. It is the peak concentration of nicotine in the brain which is responsible for reward, tolerance and addiction principle. It is absorbed in seconds throughout the body with the initial dosing.

Half-life is 2-3 hours and it is metabolized to cotinine by cytochrome P450 2A6.P 450 2A6 is also responsible for potent activation of carcinogen NNK. Clearance of nicotine is typically diurnal with midday peak and spikes of increased clearance after a meal. This explains increased smoking in the early morning, lowest in the evenings and increased smoking rate after meals [19]. There is inter-individual variation in the nicotine and cotinine metabolism addressed by varying clearance of cotinine and its effect on consumption and

dependence. The number of cigarettes smoked per day can be assessed by the plasma and urinary nicotine and cotinine concentration. Cotinine has a half-life greater than nicotine and hence used a useful biomarker in terms of smoking surveys, smoking cessation trials, and the assessment of exposure to environmental cigarette smoke. Studies done by Carabello RS et al. and Perez-stable et al. showed inter-individual variation in nicotine metabolism. They proved that nicotine intake per cigarette is significantly higher among African-Americans than Caucasian-American smokers [20,21].

Carcinogen in cigarette smoke:

An overview of the carcinogenic effect of smoking will further add to the need for this comparative study between smokers and non-smokers. A multitude of carcinogens plays a role in the development of oral and lung cancer. Apart from nicotine, there are small doses of polycyclic hydrocarbons (PAH) and NNK which are lung carcinogens on metabolic activation. There are competing detoxification pathways which differ among ethnic groups and hence differ in carcinogenic potential among individuals. Metabolic activation leads to the formation of DNA adducts which cause mutation. DNA adducts may escape DNA repair mechanisms and their existence lead to activation of oncogene or impairment of Tumor suppressor gene. There is also a mutation of human KRAS and p53 gene in smoker leading to lung cancers.



Summary of carcinogens in cigarette smoke:

Type	No. of compounds
Polycyclic aromatic hydrocarbons	10
Aza-arenes	3
N -Nitrosamines	7
Aromatic amines	3
Heterocyclic aromatic amines	8
Aldehydes	2
Miscellaneous organic compounds	15
Inorganic compounds	7
Total	55

The respiratory system is directly affected by smoking. With the alarming trend in the increase in smoking among youth the prospect of an increase in respiratory ailments in the near future is imminent. Certain parameters chest volume and its expansion are easy to perform than tedious spirometry procedure which more or less has subjective involvement. Maximal

inspiratory and maximal expiratory pressure are a simple and convenient way to measure the respiratory muscle strength. Cigarettes smoking causes a deficit in both the FEV1/FVC and MEF 25-75% suggesting it causes airway obstruction and small airway disease.

A study conducted by Tantisuwat[36] et al showed the effects of smoking on chest expansion, lung function and respiratory muscle among young people. Questions related to smoking and nicotine dependence through Fagerstrom test for nicotine dependence questionnaire.

Fagerstrom test assesses the intensity of physical dependence on nicotine. It evaluates the number of cigarettes smoked, its addiction propensity and its dependence.

The items include Yes/No questions which are marked from 0 to 1and the multiple-choice questions are graded from 0 to 3. The sum is 10 at the end of the test and its interpretation is validated. The higher the score, more intense is the physical dependence on nicotine. This was developed by Karl-Olov Fagerstrom and modified by Todd Heatherton [33,34] in 1991. This test is now copyrighted by Taylor and Francis Ltd. and can be reproduced without permission.

Fagerstrom Test for Nicotine dependence:

	Please Tick One box for each question	Score
how soon after waking do you smoke your first cigarette ?	Within 5 minutes 5-30 minutes 31-60 minutes	☐3 ☐2 ☐1
Do you find it difficult to refrain from smoking in places where it is forbidden? Church, library, etc.	YES NO	☐1 ☐0
Which cigarette you hate to give up?	The first in the morning Any other	☐1 ☐0
How many cigarettes a day you smoke ?	10 or less 11-20 21-30 31 or more	☐0 ☐1 ☐2 ☐3
Do you smoke frequently in the morning ?	YES NO	☐1 ☐0
Do you smoke even if you are sick in the bed most of the day?	YES NO	☐1 ☐0
	Total Score	

Score:

1-2 = low dependence

3-4 = low to moderate dependence

5-7 = moderate dependence

8+ = high dependence

Scoring of Fagerstrom Test for Nicotine dependence:

- Score of 1-2

A patient who scores between 1 and 2 on the Fagerstrom Test for Nicotine dependence is classified to have a low dependence- Suggests they may need nicotine replacement therapy but should be monitored for withdrawal symptoms.

- Score of 3-4

A patient who scores between 3 or 4 on the Fagerstrom Test for Nicotine dependence is classified to have a Low to moderate dependence- Should be offered patches, inhaler, lozenges or gums.

- Sore of 5-7

A patient who scores between 5 to 7 on the Fagerstrom Test for Nicotine dependence is classified to have a moderate dependence on nicotine- offered patches, inhaler, lozengesorgums. Should also offered combination therapy of patches with lozenge and gum.

- Score of 8 and over

A patient who scores between 5 to 7 on the Fagerstrom Test for Nicotine dependence is classified to have a Higher dependence on nicotine. Should be offered combination therapy of patches with lozenge and gum.

Nicotine recommendations chart:

Dependence level	Nicotine replacement therapy dosage	Combination therapy
HIGH	**Patches:** 21mg/24hr or 15mg/16hr **Inhaler:** 6 –12 cartridges per day **Lozenge:** 4mg **Gum:** 4mg	**Patches:** 21mg/24hr or 15mg/16hr AND **Lozenge or Gum:** 2mg
MODERATE	**Patches:** 21mg/24hr or 15mg/16hr **Inhaler:** 6 –12 cartridges per day **Lozenge:** 4mg **Gum:** 4mg	**Patches:** 21mg/24hr or 15mg/16 hr AND **Lozenge or Gum:** 2mg
LOW TO MODERATE	**Patches:** 14mg/24hr patch or 10mg/16hr **Inhaler:** 6 –12 cartridges per day **Lozenge:** 2mg **Gum:** 2mg	**Patches:** 14mg/24hr or 15mg/16hr AND **Lozenge or Gum:** 2mg
LOW	May not need NRT Monitor for withdrawal symptoms **Patches:** 7mg/24hr patch or 5mg/16hr **Lozenge:** 2mg **Gum:** 2mg	

‘FOUR Cs’ Test

DSM IV has laid down criteria in terms of 4C ’s which are conveniently labeled as Compulsion, control, cutting down, and consequences.

1. Compulsion - The intensity with which the desire to use a chemical overwhelms the patient's thoughts, feelings, and judgment.

2. Control - The degree to which patients can (or cannot) control their chemical use once they have started using.

3. Cutting down - The effects of reducing chemical intake; withdrawal symptoms.

4. Consequences - Denial or acceptance of the damage caused by the chemical.

TO assess these parameters physicians approach the patients in terms of questions. Assessing Nicotine Addiction Using the “Four Cs” Test

Compulsion
• Do you ever smoke more that you intend?
• Have you ever neglected a responsibility because you were smoking, or so you could smoke?
Control
• Have you felt the need to control how much you smoke but were unable to do so easily?
• Have you ever promised that you would quit smoking and bought a pack of cigarettes that same day?
Cutting down (and withdrawal symptoms)
• Have you ever tried to stop smoking? How many times? For how long?
• Have you ever had any of the following symptoms when you went for a while without a cigarette: agitation, difficulty concentrating, irritability, mood swings? If so, did the symptom go away after you smoked a cigarette?
Consequences
• How long have you known that smoking was hurting your body?
• If you continue to smoke, how long do you expect to live? If you were able to quit smoking today and never start again, how long do you think you might live?

Many assessments have come out in a prolific way to set standards into smokers' profile; which available for patient's use.

Smoker's Profile[35]**:**

Stress relief
• When you're frustrated or angry, do you automatically think about smoking a cigarette?
• If you're upset or scared, does a cigarette help you calm down?
• Do you rely on cigarettes when you're under stress?
• Recall a time when you stopped smoking for a while. After you stopped smoking, did you want a cigarette more whenever you got upset or angry? Did you miss cigarettes more when you were under a lot of stress or tension?
Conditioned responses
• How often do you smoke while you're driving a car or drinking a cup of coffee?
• If you're with someone who's smoking, do you automatically smoke, too?
• Do you usually smoke a cigarette during or after a meal?

• Recall a time when you stopped smoking for a while. Did being around smokers make it hard to not smoke? Were there certain people, places or things that made you want to smoke?
Relief of withdrawal symptoms
• When do you smoke your first cigarette of the day?
• Do you get irritable if you have to go more than two hours without a cigarette?
• Do you have trouble concentrating if you're not smoking?
• Recall a time when you stopped smoking for a while. Did you get irritable or moody during the first few days after you stopped? Did you have trouble concentrating during the first few days after you stopped?
Elevation of depressed mood
• Recall a time when you stopped smoking for a while. Did you become more depressed?
• When you woke up in the morning, did you feel that you could spend all day in bed?
• How was your energy level after you stopped smoking?

After assessing the Smoker's profile need to assess the readiness to change. Mere question of 'Do you smoke?' gathers information about smoking but not the cognitive aspect of smoking. This continuum of change in smoking pattern can be staged into Precontemplation, contemplation, preparation, action, maintenance and relapse.

Summary of Physician Counselling Based on the Stages of Change

STAGE OF READINESS	PATIENT RESPONSE TO: "WHAT ARE YOUR THOUGHTS AND FEELINGS ABOUT QUITTING SMOKING?"	GOAL OF INTERVENTION	TYPICAL PHYSICIAN INTERVENTION
Precontemplation	"I like to smoke."	Introduce ambivalence	"Your emphysema will improve after you've quit smoking."
Contemplation	"I like to smoke, but I know I need to quit."	Resolve ambivalence	"How will your life be better after you've quit smoking?"
Preparation	"I'm ready to quit."	Identify successful strategies	"Choose a 'quit day' and let's make plans for it."
Action	"I'm not smoking, but I still think about smoking from time to time."	Provide solutions to specific relapse triggers	"How can you deal with your desire to smoke in those situations?"
Maintenance	"I used to smoke."	Solidify patient's commitment to a smoke-free life	"This would be a good time to share your experience with other people."

The goal of counselling patients is to assess their previous attempts tom quit and identify what have worked and take actions accordingly.

Chronic Obstructive pulmonary disease (COPD):

COPD is characterised by a preventable and treatable disease associated with airflow limitation that is not fully reversible [22]. This progressive airflow limitation is due to the noxious effects of smoke that damages the fragile environment of the lungs. The loss of lung function is addressed in terms of narrowing of airways, lung parenchymal destruction which leads to compliance and elasticity defects and vascular bed damages characterised by increased pressures.COPD was ranked 6th commonest cause of death in 1990 by the global burden of disease studies.

It is projected to become the 3rd cause by 2020 and 5th most common cause of chronic disability by 2020 (23).Estimates from WHO suggest that 90% of COPD related deaths occur in low and middle-income countries with India and China mounting to 66% of global COPD mortality(24).COPD along with asthma and respiratory illness is the second leading cause of death among the population aged 25-69 years in India [25]. The prevalence of COPD is on rising and expenditure associated with its treatment is more than other common respiratory ailments. The global increase in COPD is due to continuous cigarette smoking, the longer survival rate particularly in developing nation like ours. There has been a touch of neglect in addressing the problem of COPD at the global level by the doctors, researchers and the pharmaceutical

companies because the underlying disease process is irreversible. Current treatment modalities treat the exacerbation associated with COPD the disease per se. The need for concrete COPD treatment underlies the fact that many are affected due to environmental factors. Indeed 10% of non-smokers and many among women with biomass exposure have COPD.COPD with non-smoking causes needs more attention. Developing countries have a much higher burden with non-smoking causes of COPD than the developed world. Hence more detailed research in terms of the molecular and cellular level is needed to curb this epidemic of COPD globally.

Epidemiological studies have shown that death from COPD is due to an accelerated decline in lung function test. There is 50-100 ml of loss in FEV1 every year compared to less than 30 ml in normal individuals. According to studies done by Celli et al., other factors like exercise capacity, exacerbation frequency, and associated systemic illness may indicate poor prognosis [26]. Treatment modalities start with smoking cessation. Unfortunately, abstinence from smoking cigarettes has a poor success rate as the quitting rate is around 15% and several studies have shown smoking cessation fail to reverse inflammatory changes in patients. Bronchodilator therapy is the mainstay of therapy but with little benefit in the long-term course.

Magnitude of COPD and its economic burden in India:

According to ICMR-PHFI-IHME 2017 data, COPD is the second biggest cause of death in India among Non-communicable diseases [27]. It is the

4th leading cause of years of life lost in Empowered Action Group (EAG) states. COPD ranked 7th in North-Eastern states and 4th in other states among all causes of years of life lost. COPD and its exacerbation require frequent hospitalisation which sometimes needs costly intervention putting the burden on the existing resource-limited health care in our country. Elderly people, more than 65 years are admitted at a rate 4 times higher than younger ones with a mean length of hospital stay ranging from 4 to 16 days. Social structure in India limits the utilisation of health care by the elderly at their will and this adds to their misery of with COPD. Strategies tackling at early intervention with solid scientific background supporting smoking cessation will play a major role in healthy society.

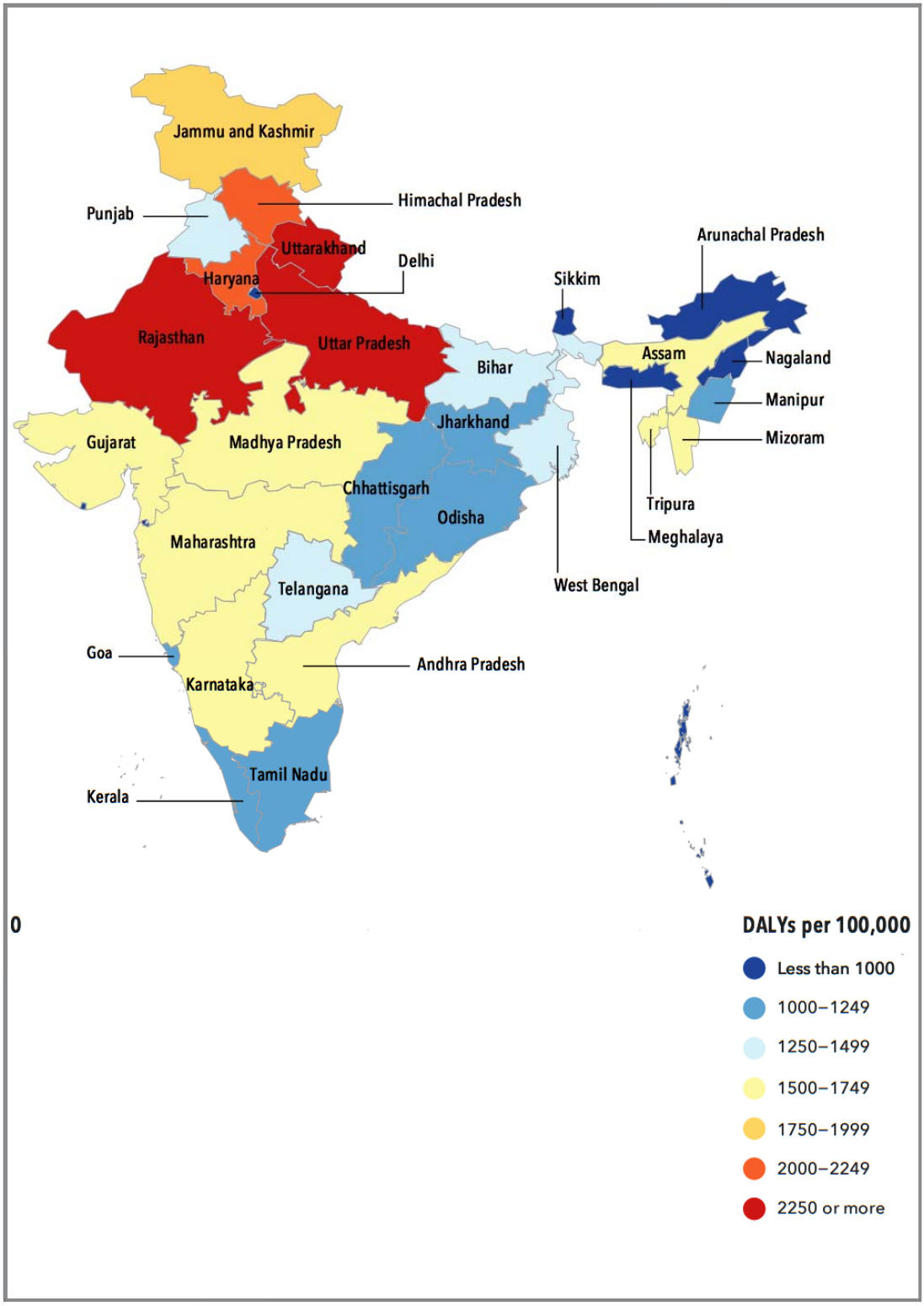
How to tackle COPD problem:

To increase awareness among the healthcare individuals, public and government organisations. To educate general practitioners to recognise COPD early and institute therapy at the earliest. To stop smoking as early as possible in patients with the early disease has clear benefits. The attitude that self-induced smoking habit is creating such a health issue and hence it needs less emphasis has to be changed. Tobacco use and biomass smoking in households need to be curtailed.

There should be better intervention and supportive care at the primary health center level to minimise the logistic difficulties in obtaining expert views. Everyone in the healthcare system should gain sufficient knowledge in

attending to patients with COPD in terms of early diagnosis. To impart avoidance of risk factors and routine monitoring during follow up to assess the dependence will motivate patients to lead a healthy lifestyle. This is particularly important among smokers with COPD. India with its diverse culture and regional background smoking cessation is a serious challenge with the high-cost delivery of cure. At every District level, separate emphasis on treatment in view of emergency intensive care units with all life-saving equipment in adequate numbers to all needy COPD patients will alleviate the mortality rate and quicker recovery time.

With time and then we have been successful in health-related schemes and adding up COPD to TB control and other important national programmes will be of significance.


Jammu and Kashmir
Himachal Pradesh
Punjab
Uttarakhand
Delhi
Haryana
Rajasthan
Uttar Pradesh
Bihar
Sikkim
Arunachal Pradesh
Assam
Nagaland
Manipur
Mizoram
Tripura
Meghalaya
Jharkhand
Gujarat
Madhya Pradesh
Chhattisgarh
Odisha
Maharashtra
Telangana
West Bengal
Goa
Andhra Pradesh
Karnataka
Tamil Nadu
Kerala
0
DALYs per 100,000
Less than 1000
1000–1249
1250–1499
1500–1749
1750–1999
2000–2249
2250 or more

Pulmonary Function tests (PFT):

It is a valuable investigation in the management of respiratory illness. But its use in routine clinical setting is subject to question.PFT aid in diagnosis, treatment and its response. Basic respiratory physiology is the cornerstone in understanding the pulmonary function test and its interpretation. These tests indirectly give information on large and small airways, the parenchyma, and the integrity of the vascular bed. They do not provide concrete diagnosis per se but provide pattern on various abnormalities. European Respiratory and American Thoracic Societies have provided guidelines on performing PFTs [2]. It is effort dependent and hence full cooperation the patient is necessary.

Indications for performing Pulmonary function tests:

Investigation of patient with symptoms/signs/investigations that suggest pulmonary disease:

- Cough
- Wheeze
- Breathlessness
- Crackles
- Abdominal chest X-ray

Patients with pulmonary disease; monitoring and response to treatment; progression of the disease:

- Interstitial fibrosis
- COPD
- Asthma
- Pulmonary Vascular disease

Investigation of patients with disease that may have a respiratory complication:

- Connective tissue disorders
- Neuromuscular diseases

Preoperative evaluation prior to

- Lung resection
- Abdominal surgery
- Cardiothoracic surgery

Evaluation of patients at risk of lung diseases:

- Exposure to pulmonary toxins such as radiation
- Medications with pulmonary side effects
- Environmental or occupational exposure

Contraindications for Performing PFTs [28]:

- Myocardial infarction within last month
- Unstable angina
- Recent Thoraco-abdominal surgery
- Recent Ophthalmic surgery
- Thoracic or abdominal surgery
- Current pneumothorax
- Thoracic aneurysms

Patients with active respiratory infection are deferred from performing investigation until risk of cross contamination is negligible. Sitting position is typically used to prevent risk of falling and injury in the event of syncopal episode.

Patients are not advised to smoke for at least 1 hour before the procedure, not to eat large meals 2 hours before their procedure and not to wear tight fitting clothes as these factors may influence the test findings.

False teeth are left in place unless the prevent the patient from forming an effective seal around the mouth piece.

Normal or predicted values from large population studies are taken and values are taken for people matched for height, sex, age and in some cases

ethnicity. Test should be performed three times to ensure that the results are constantly reproducible with less than 200 ml variation. Dynamic studies are performed first and other aspects of PFTs are taken subsequently.

Spirometry

Spirometry is used measure lung function. Simple and quick if done with full cooperation of the patient. Patients are asked to take maximal respiration and then to expire forcefully.

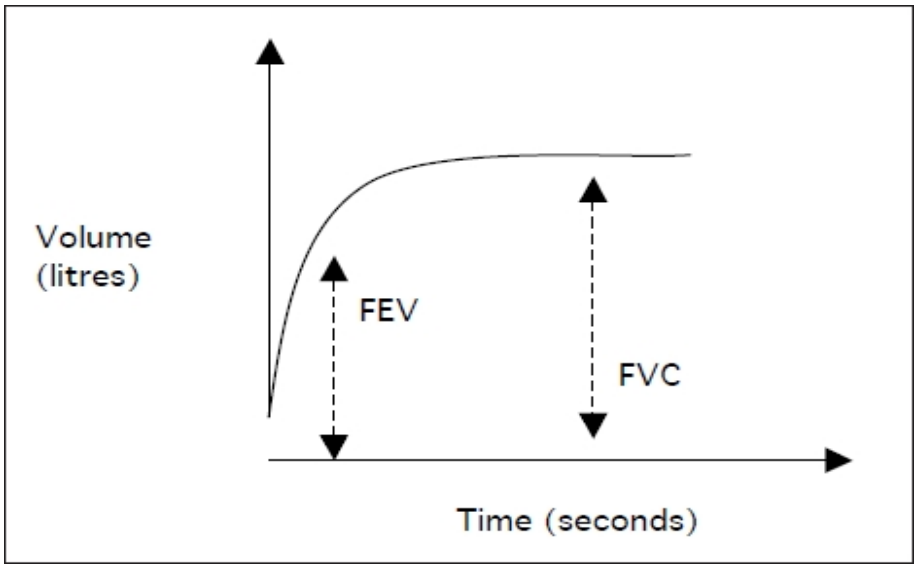


Fig-Normal Spirometry

Measurements made by spirometer:

- Forced expiratory volume in one second (FEV1).
- Forced vital capacity.
- The ratio of the two volumes (FEV1/FVC)

Spirometric Values:

1. FVC - Forced vital capacity; the total volume of air that can be exhaled during a maximal forced expiration effort.

2. FEV1 - Forced expiratory volume in one second; the volume of air exhaled in the first second under force after a maximal inhalation.

3. FEV1/ FVC ratio—The percentage of the FVC expired in one second.
4. FEV6 - Forced expiratory Volume in 6 seconds
5. FEF 25-75% - Forced expiratory flow over the middle one half of the FVC.

   The range at which 25 percent to 75 percent of air is exhaled.
6. MVV - Maximal voluntary Ventilation.

Lung Volumes:

1. ERV - Expiratory reserve volume; the maximal volume of air exhaled from end-expiration.
2. IRV - Inspiratory reserve volume; the maximal volume of air inhaled from end-inspiration.
3. RV - Residual volume
4. VT - Tidal volume

Lung Capacities:

1. FRC - Functional residual capacity; the volume of air in the lungs at resting end-expiration.
2. IC - Inspiratory capacity; the maximal volume of air that can be inhaled from the resting expiratory level.
3. TLC - Total lung capacity; the volume of air in the lungs at maximal inflation.
4. VC - Vital capacity; the largest volume measured on complete exhalation after full inspiration.

The basic idea of spirometry is top measure the changes in lung volumes during forced expiratory and inspiratory manoeuvres. It begins by asking the patient to undergo full inspiration and asked tom rapidly exhale the air. This exhalation is asked to prolong as much as possible. This effort is recorded, and it is computerised for better viewing of the curves and the final results. The total lung capacity is calculated with the addition of the main 4 volumes

1. ERV - expiratory reserve volume
2. IRV - inspiratory reserve volume
3. RV - residual volume
4. TV - tidal volume

The most important spirometric value is the FVC and the manoeuvre done for its measurement is most crucial in the process. During rapid

exhalation lung tends to exhale 80% of the air within the first 6 seconds or less. FEV1 is the Forced expiratory volume in the first second of FVC.

FEV1/FVC is an important parameter extrapolated in this setting.

Normal Values of Pulmonary function tests:

Pulmonary function tests	**Normal values**
FEV 1	80-120%
FVC	80-120%
Absolute FEV1/FVC	Within 5% of the predicted ratio
TLC	80-120%
RV	75-120%
DLCO	>60% to <120%

The ratio primarily helps in the identification of an obstructive or restrictive pattern of disease. When FEV1 is reduced more than FVC it signifies obstructive pattern of pathology (ratio < 70%). Examples include Obstructive defects like chronic obstructive pulmonary disease and asthma. The ratio can further classify the degree of obstruction. The ratio of FEV1/FVC >70% with FVC reduced more than FEV1 suggests a restrictive pattern of diseases such as interstitial lung disease and chest wall deformities.

FEV1 % predicted	Stage
> 80%	Mild
50-79%	Moderate
30-49%	Severe
<30%	Very Severe

Table: Severity of airflow obstruction based on percentage predicted FEV1.

The most disease patterns fall into these categories. This is calibrated to the population pattern and subjected to a standard set by the international organization. Every value is comparable with age, sex, and other physical variables.

Interpreting spirometry results:

Determine whether the test results are interpretable.

Assess the FVC, FEV1 and absolute FEV1/FVC ratio.

1. Normal Spirometry - FVC normal; FEV1 normal; and absolute FEV1/FVC > 0.7

2. FVC decreased; FEV1 decreased or normal; absolute FEV1/FVC >0.7

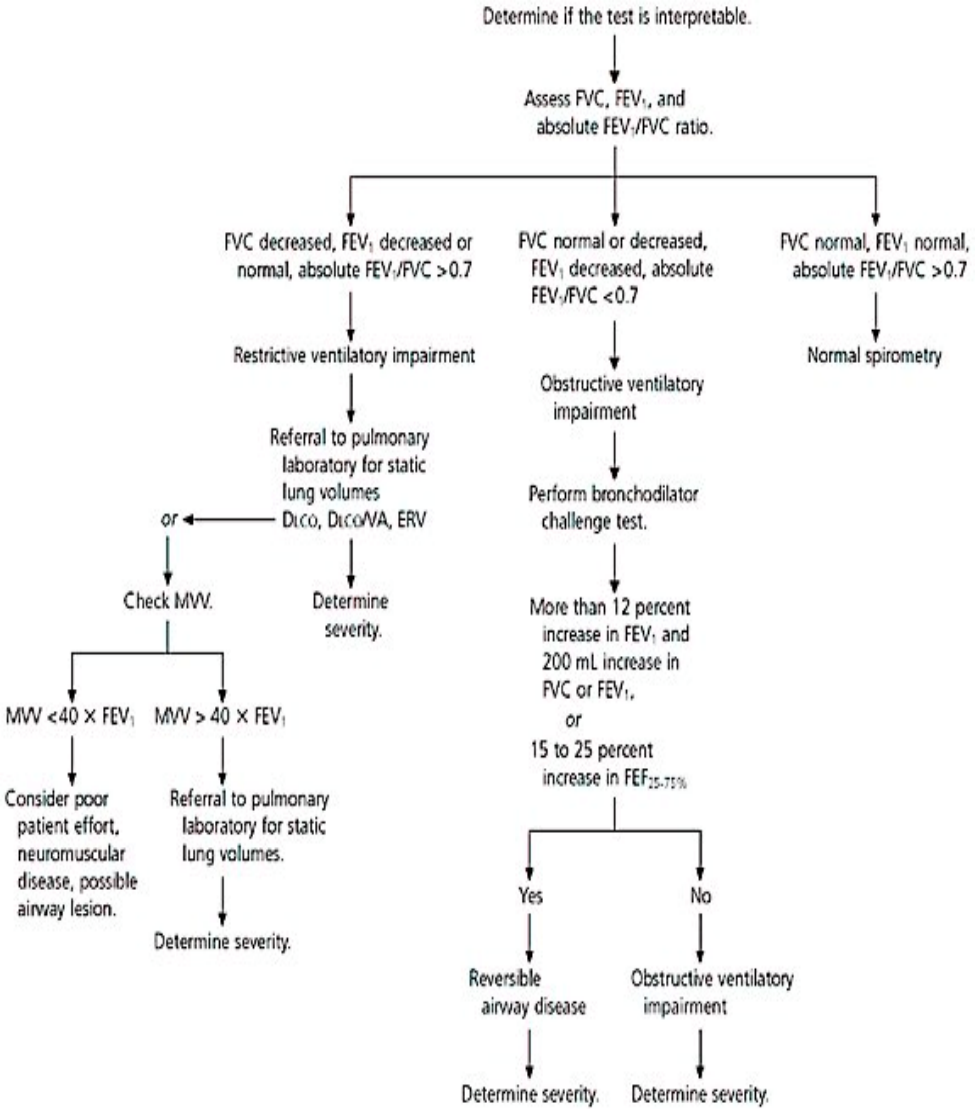
   Suggests Restrictive ventilatory impairment

Further referral to pulmonary laboratory for static ling volumes DLCO, ERV and check for MVV.

3. FVC normal or decreased; FEV1 decreased; Absolute FEV1/FVC < 0.7 suggests obstructive ventilatory pattern. Then bronchodilator challenge test.

   Here in this test, a 12 percent increase in FEV1 and increase in FVC or FEV1at around 200 ml suggests a reversible airway disease.,

Algorithm for interpreting results of spirometry.



At least 3 acceptable spirographs must be obtained for the validity of the spirometric results. The test session is finished when the difference between largest FVC measurements and between two largest FEV measurements within the 0.2 liters .8 attempts are performed to meet the above criteria.

When the test is said to be valid, the second step is to determine whether an obstructive or restrictive pattern is noted.

When the FVC and FEV1 are decreased, the absolute FEV1/FVC ratio helps us to differentiate between obstructive and restrictive pattern. FEV1/FVC is normal or increased it is a restrictive pattern. Then the patient is referred to the Pulmonary laboratory for static lung volumes. If Total lung capacity is less than 80%, it is a restrictive pattern.

In this case diseases like pneumonia, pleural effusion, pulmonary fibrosis, and congestive heart failure are taken into consideration.

The obstructive pattern is recognized by the reduced FEV1 and FEV1/FVC ratio.

Bronchodilator challenge test is recommended to detect patients with reversible airway obstruction like asthma. The patient should not have used bronchodilator for at least 48 hours before the test is performed. In this bronchodilator challenge test, a bronchodilator is given, and spirometry is repeated after some time. A positive test is implied by an increase in FEV1 by 12% and FVC increased by 200mL.

Mid-expiratory flow rate (25-75%) is the average forced flow rate over the middle 50% of the FVC. This helps in the diagnosis of the obstructive pattern. Under a strong clinical suspicion, a reduction in MEF 25-75% of less than 60% and FEV1/FVC reduced may confirm airway obstruction.

Maximal voluntary ventilation maneuver is done to confirm restrictive and obstructive patterns. The participant is asked to breathe as hard as possible

for 12 seconds. The results are further interpreted for 60 seconds and reported in liters per minute.

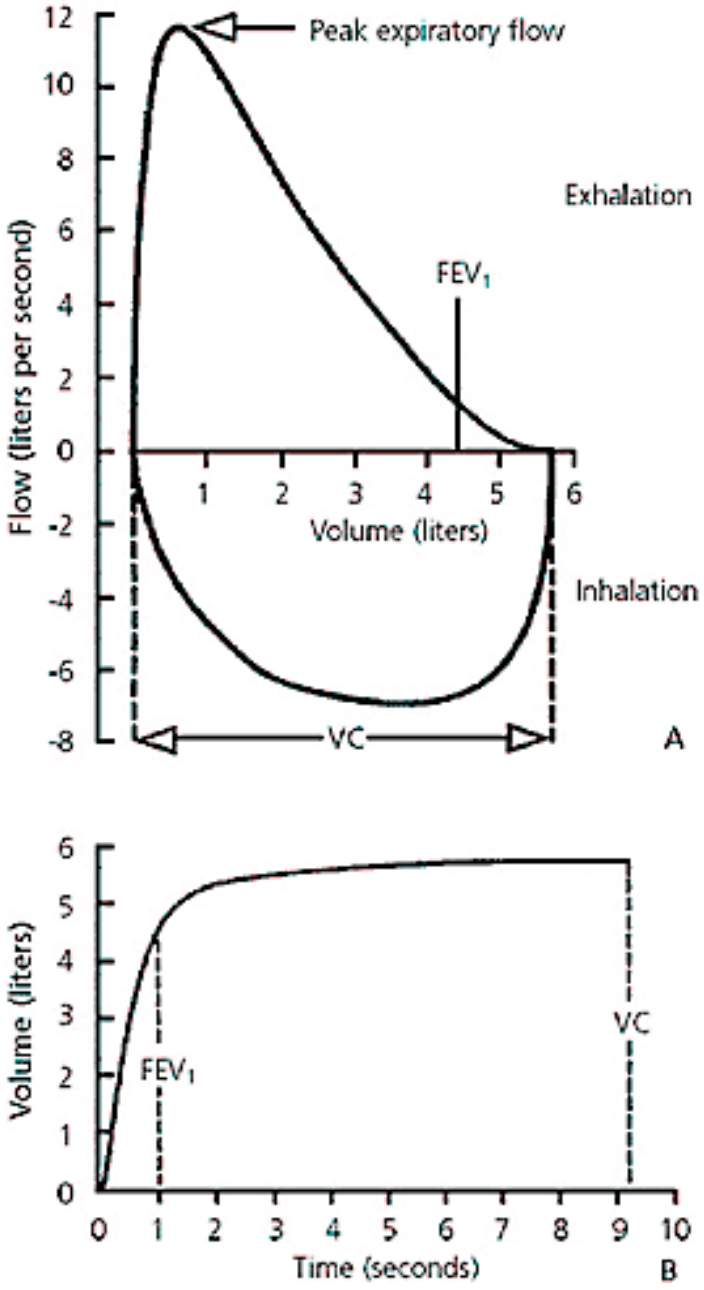
MVV is approximately 40 times FEV1. A low MVV can occur in obstructive disease but more common in case of a restrictive pattern. When MV is low and other parameters like FEV1 and FVC are normal suggests poor patient effort, major airway lesion or neuromuscular defect.

MEF 25-75 represents the forced expiratory flow between 25% and 75% of Vital capacity and reflects the small airway patency. Smoking leads to a particular decline in the lung function. The obstruction in the airflow is primarily due to the abnormalities in the airways less than 2mm in internal diameter.

Chronic inflammation of membranous and respiratory of bronchioles. The smokers have fewer PFT values in all the parameters compared to non-smokers.

Younger smokers have lesser values compared to elderly smokers. The reduction in MEF 25-75 among smokers were significantly lower due to the involvement of the smaller airways. With salbutamol challenge of around 200 mcg, there was some reversibility noted in smokers. This proves that smaller airways are more susceptible to airway reversibility to salbutamol and smoking cessation.

Normal Flow volume loop:

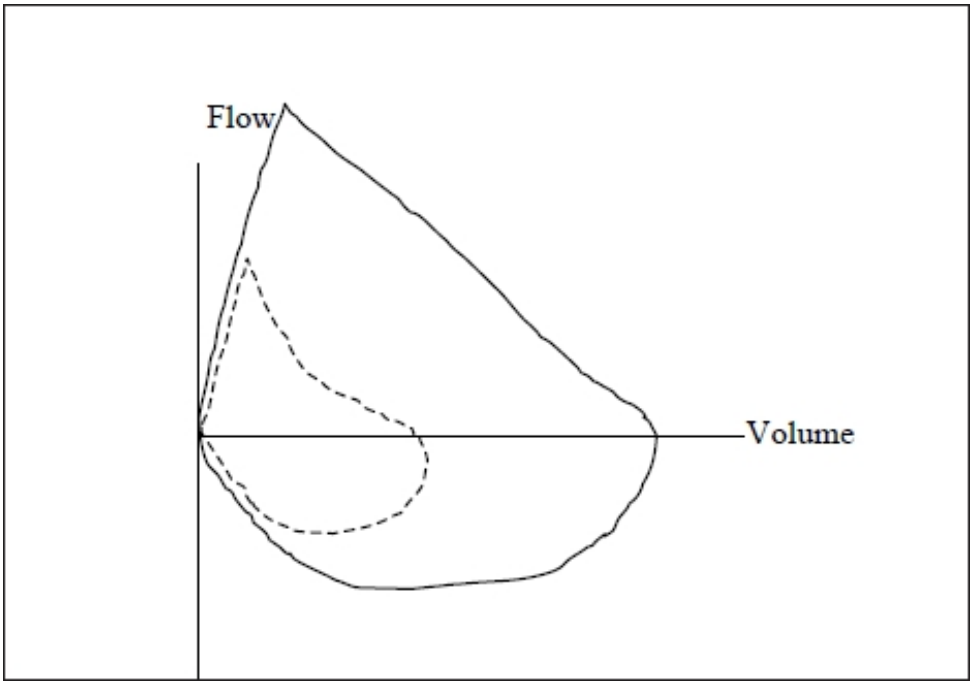


The normal Spirometric flow diagram.

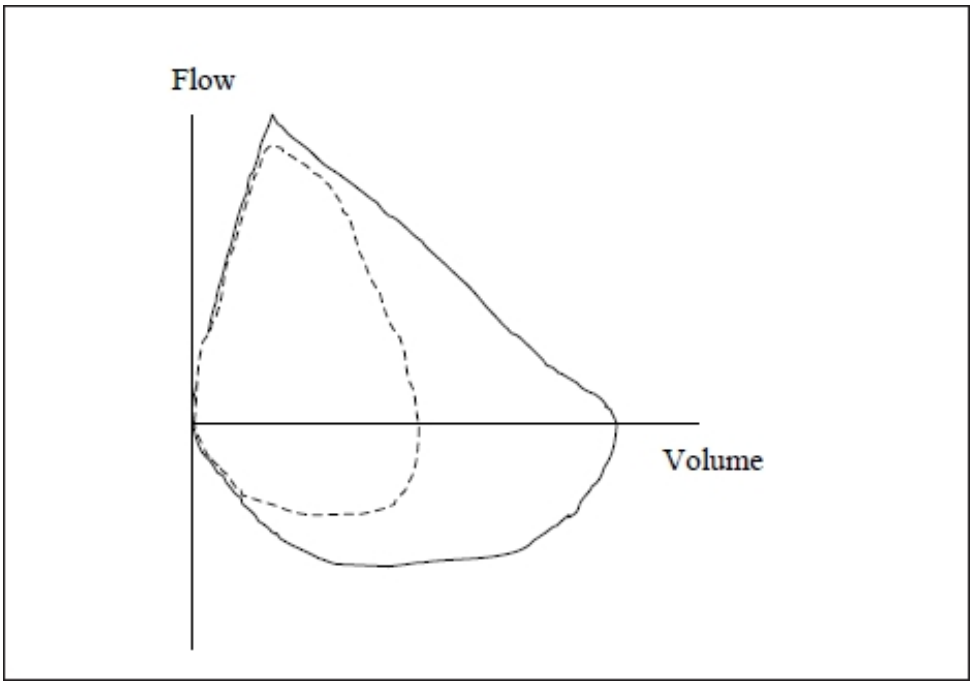
A- Flow volume curve

B - Volume-time curve.

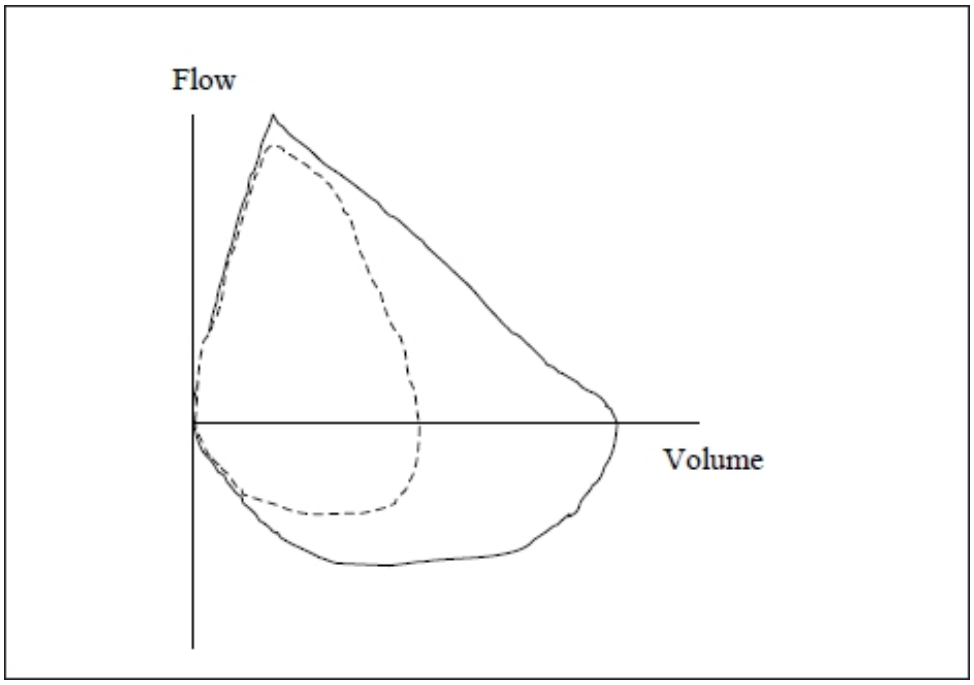
The smooth lines, expiratory time of greater than 6 seconds, and quick peak of expiratory flow rate is a good spirometric effort.



Flow volume curve in Obstructive lung disease:



Flow volume curve in Restrictive lung disease:



Flow volume curve in Intra-thoracic airway obstruction:

PFTs take 15 minutes for adults,15-30 minutes for children,45 minutes for Pre and post bronchodilator testing.

Within the manoeuvre criteria for reproducibility and acceptability following things are considered:

Individual spirograph are acceptable if

1. They are free from artefacts

- Cough during the first second of exhalation
- Glottis closure that influences the measurement
- Early termination or cut off
- Leak
- Obstructed mouthpiece

2. They have good starts

- Extrapolated volume <5% of FVC or 0.15 liters, whichever is greater

3. They have satisfactory exhalation

- Duration of > 6 seconds (>3 seconds for children) or a plateau in the volume - time curve or if subject cannot or should not continue to exhale.

Between manoeuvre criteria:

1. After three acceptable spirograph have been obtained, apply the following tests

   - The two largest values of FVC must be within 0.150 liters of each other
   - The two largest values of FEV1 must be within 0.150 liters of each other

2. If both of these criteria are met test session may be concluded.

3. Total of eight tests can be performed.

The technical difficulties in conducting these tests can be alleviated by proper education of the patients regarding the procedure. This helps the patient ti psychologically handle the stress in doing the procedure.

Lot of effort is needed in educating the patients about the procedure and skillful assistants are important in this process.

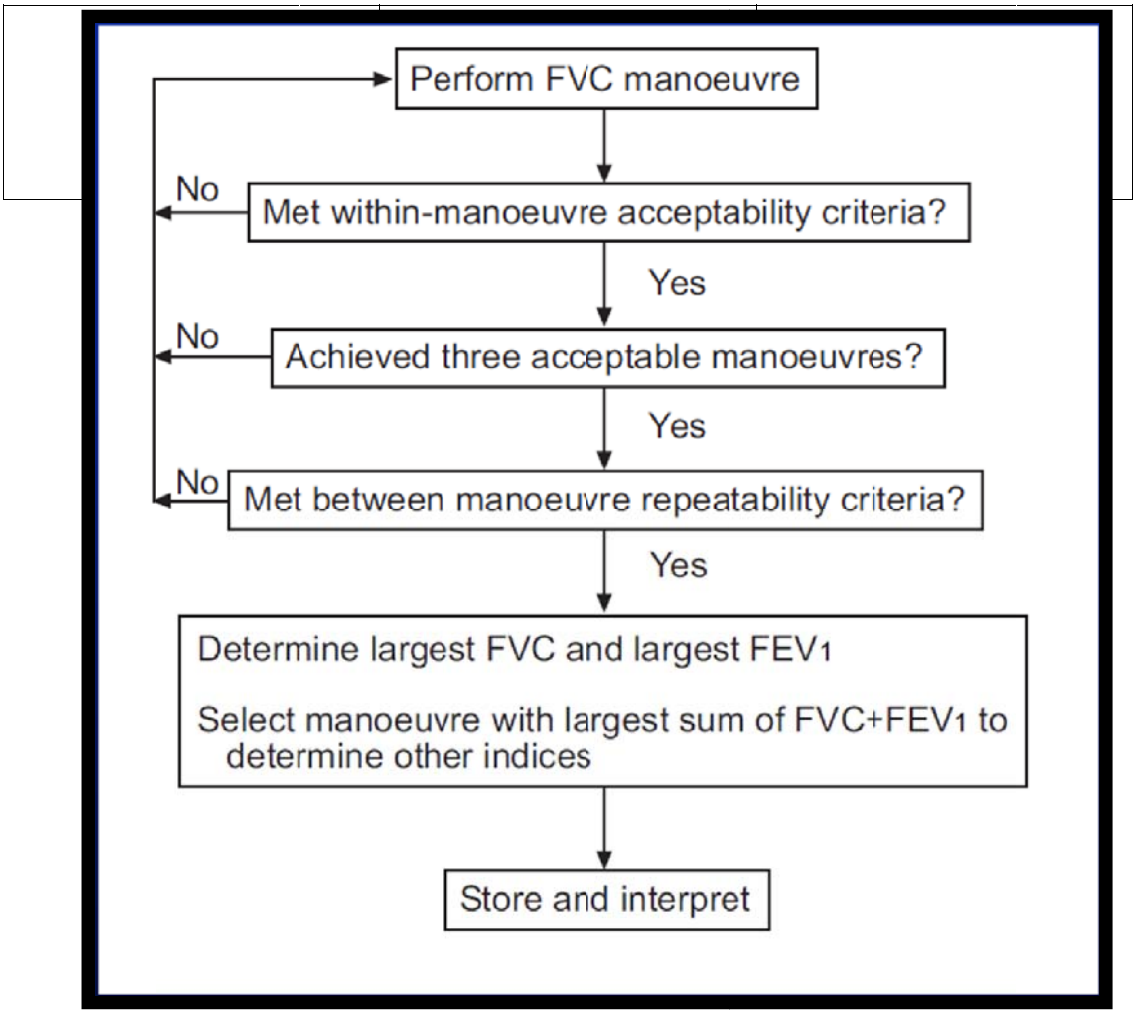
The proper ambience and quiet place are important in the analysis of the spirometry.

Best results are obtained from best support team and very good ambience. The best possible results help in unmasking the COPD in early stages.

Multitude of parameters are considered, and all are resulted in computerised manner to get the better results.

Equipment quality control:

Multitude of tests are done at regular intervals to check the proper functioning of the spirometry.



Volume	Daily	Calibration check with a 3-litre syringe
Leak	Daily	3 cmH20 (0.3 kPa) constant pressure for 1 min
Volume Linearity	Quarterly	1-litre increments with a calibrating syringe measured over entire volume range
Flow linearity	Weekly	Test at least 3 different flow ranges
Time	Quarterly	Mechanical recorder check with stopwatch
Software	New versions	Log installation date and perform test using “known” subject.

These tests are done ensure the proper results and hence correlates with the diagnosis through this tedious spirometry procedure

A study done by Zhang et al compared clinical features between non-smokers with COPD and smokers with COPD [29]. They concluded Non-smokers had less impairment of airflow and gas exchange. There was a lesser prevalence of emphysema, chronic cough, and sputum among non-smokers compared with smokers. Comorbidities including hypertension, diabetes and coronary heart disease were not significantly different between the two groups

in the study. Patients with COPD are at increased risk of developing Myocardial infarction, angina, osteoporosis, bone fractures, depression, respiratory infections, and diabetes. It may contribute to these comorbidities through its extrapulmonary effects such as malnutrition and skeletal muscle dysfunction. Tobacco causes goblet cell hyperplasia and chronic hypersecretion of mucus and it is evident by the results from the study showing more chronic cough and phlegm among smokers than non-smokers. The extracellular matrix destruction in terms of poorer diffusion capacity on lung function test and more emphysema on X-ray is seen more often with smokers.

Asthma, congestive heart failure, congestive heart failure, tuberculosis, diffuse pan bronchiolitis, bronchiolitis are mentioned as the differential diagnosis for COPD in GOLD criteria. Spirometry is essential for the diagnosis of COPD and its confirmation. Some tools are developed for screenings spirometry has its disadvantages in terms of cost and logistics. Hence questionnaire was developed to identify patients at risk of developing COPD.

Lung function questionnaire (LFQ) items were identified during the empirical phase (version 1) and the revised lung function questionnaire (Version 2) from physician and patient inputs.

Version 1	Version 2
Do you currently smoke?	Do you frequently cough up mucus?
How many years have you smoked?	Does your chest often sound noisy (wheezy, whistling) when you breathe?
When smoking, about how many cigarettes were or are typically smoked each day?	Do you experience shortness of breath upon physical exertion (walking up a flight of stairs or walking up an incline without stopping to rest)?
Troubled by shortness of breath when hurrying on level ground or walking up a slight uphill?	What is your age range?
When you develop cold, does your respiration sound wheezy or noisy?	How many years have you smoked?
Do you cough out sputum for days for 3 consecutive months or more during a year?	When smoking, about how many cigarettes were or are typically smoked each day?
What is your age range?	Do you currently smoke?

As spirometry is not practical in all settings. Hence these set of items identifies patients with spirometry-based obstruction and for potential inclusion in the LFQ.

These parameters include

1. Age
2. Occurrence of wheezing
3. Phlegm
4. Dyspnea
5. Smoking history.

This LFQ can be used in primary care settings as a screening tool and identify the patients at earliest to identify patients with obstruction. This LFQ has adequate accuracy, sensitivity, and specificity.

An 11-questionnaire was developed to grade COPD and it includes qualitative and quantitative analysis of the patient. Among the 11 questions, five are related to respiratory symptoms. Others include patient background and other details related to COPD. General symptoms like fatigue, insomnia, irritability, and anxiety were not included as these may interfere with other disease processes too.

This test is particularly helpful in elderly and it correlates with dyspnea and palpitation more with COPD than ischemic heart disease. It is less time consuming as it takes less than 5 minutes to complete and easy at the level of primary care settings. Scoring systems of the 11 items on the Questionnaire for the efficient screening of COPD:

1. Average number of cigarettes per day, then multiply by your smoking duration in years.

   0: less than 200

   1: 201-400

   2: 401-600

   3: 601-800

   4: 801-1000

5: 1001-1200

6: 1201-1600

7: over 1601

2. How old are you?

0: under 50

1: 50-59

2: 60-69

3: 70-79

4: over 80

3. Do you experience sputum (phlegm) or coughing every day?

0: not at all

1: Small amounts of sputum or coughing during the day

2: moderate amounts of sputum or coughing during the day

3: Large amounts of sputum or coughing during the day

4. Do you experience episodic wheezing?

0: Not at all

1: seasonally

2: When climbing stairs or slopes

3: When changing clothes

4: Frequently during the day

5. Do you experience dyspnea on exertion?

0: No dyspnea when climbing a flight of stairs, while carrying baggage.

1: Feel dyspnea at the top of a flight of stairs, while carrying baggage.

2: No dyspnea until the top of a flight of stairs, without any rest.

3: Require a rest when climbing a flight of stairs.

4: Require two or more rests before the top of a flight of stairs.

5: Unable to climb a flight of stairs in any case.

6. Do you experience any palpitations (rapid heart rate).

0: Not at all

1: when climbing up slopes or stairs

2: When walking on flat surfaces

3: Always.

7. Is your sleep ever disturbed by episodic dyspnea?

0: not at all

1: Once a month

2: Occasionally

3: Frequently

8. Did you suffer from occasional common colds, asthma attacks or pneumonia in your childhood?

0: No

1: Yes

9. Have your parents or siblings experienced asthma attacks or complained of dyspnea?

0: No

1: Yes

10. Are you exposed to dust or heavy traffic in your home or working environment?

0: No

1: Yes

11. Are you excessive underweight or overweight?

0: No

1: Yes

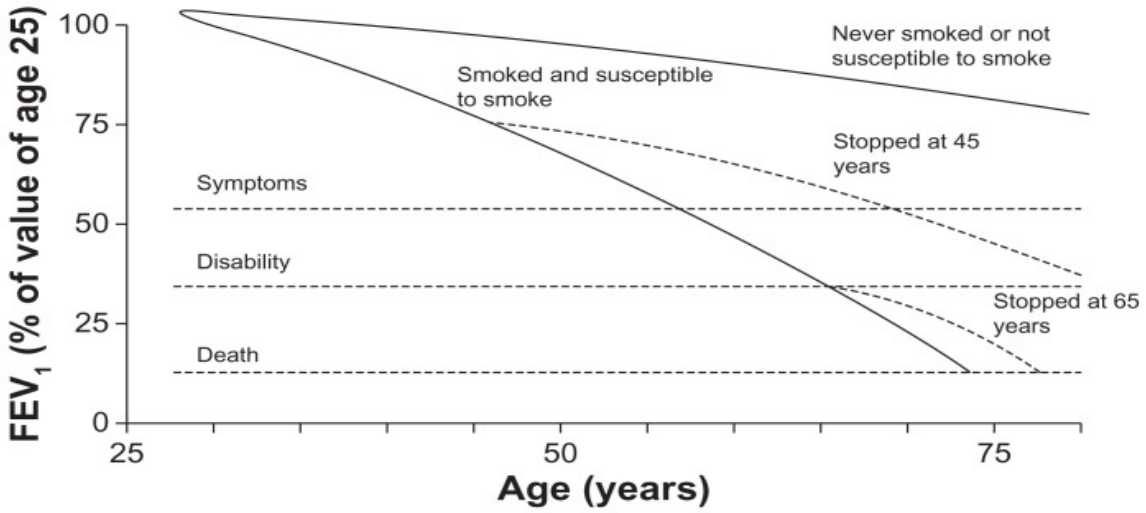
This questionnaire further enhances the physician and patient participation in the nicotine addiction and helps in smoking cessation.

Lung function decline in COPD was done by landmark study of Fletcher and Peto[31]on the natural history of tobacco smoke-related chronic airflow

obstruction. There is a decline in the forced expiratory volume in the first second (FEV1) in the COPD. The decline in the FEV1 slow in the beginning and begins faster with a more advanced disease. The mean rate of decline in GOLD stages II and III is between 47 and 79 ml/year and 56 and 59 ml/year respectively. This decline his lower than 35 ml/year in stage IV. Every 6 months for an 8-year follow up period well-known graph was obtained and let to the understanding of the COPD pathologic process.

Information obtained from Fletcher and Peto work are:

- Individuals susceptibility to smoking-related lung damage
- The progression of the airflow obstruction once COPD is diagnosed.
- Variability in abnormal lung function and its decline among patients.
- Reduction of excessive FEV1 decline after smoking cessation at all times.
- A rarity of self-reported symptoms when airflow reduction is mild to moderate.



Modified Fletcher and Peto's Graph

This Modified curve of Fletcher and Peto suggested smoking cessation at an earlier age is more beneficial than at later stage in regard to retardation of obstructive changes. Likewise, cessation of smoking before 40 years is more beneficial than later.Any intervention done after 50 percent of lung loss is not fruitful is patients' symptomatic relief and projects a bad prognosis.

Limitations of Fletcher and peto's curve are

1. All subjects were males
2. Age of recruitment was between 30 and 59
3. Follow up period was short compared with the large time range shown on the X-axis of the graph.
4. Curves were extrapolated backward and forward with inaccuracies leading to distorted inference.

5. These findings suggest major therapeutic efforts at the level of severe to very severe obstruction in COPD.

These limitations were further supported by large amounts of data collected to challenge this hypothesis on the basis of Fletcher and Peto's curve.

In a study conducted by Dawkins et al showed an interesting data on the decline in lung function in patients with alpha 1 antitrypsin deficiency-related emphysema in terms with GOLD criteria [32]. In patients with PiZ phenotype, the mean annual decline in FEV 1 was correspondingly higher when compared with general COPD patients.

Rate of annual decline of the forced expiratory volume in the first second (FEV1) in Global Initiative for Chronic Obstructive Lung Disease (GOLD) stage I–IV chronic obstructive pulmonary disease patients with alpha-1-antitrypsin deficiency-related emphysema measured during a longitudinal study with a 3-year follow-up period:

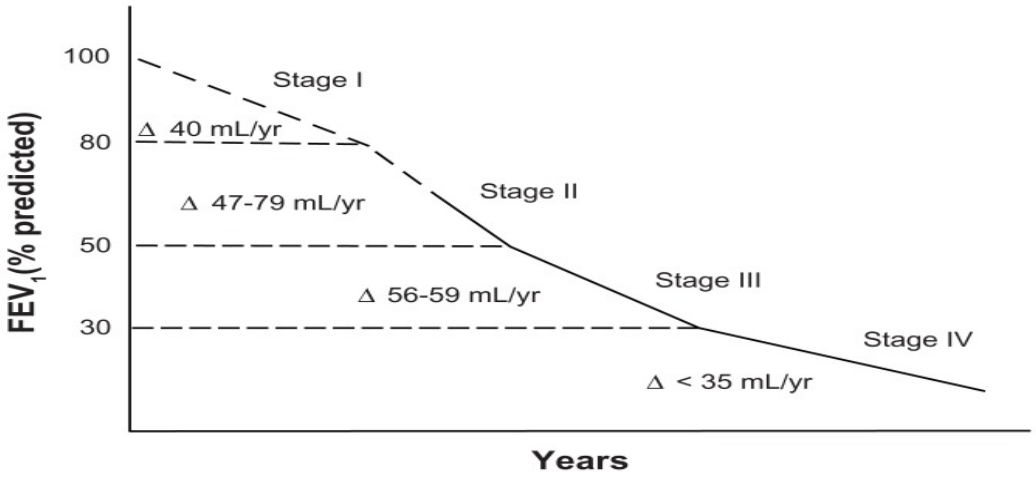
GOLD stage	**No of patients**	**Age range (yr)**	**Mean FEV1 decline (mL/yr)**
I	18	49 ± 9	32 ± 19
II	26	51 ± 9	90 ± 19
III	38	53 ± 11	52 ± 8
IV	19	49 ± 9	8 ± 9

Similar cohort studies were done and provided data in lung function decline in COPD patients.

Reference	Study	GOLD stage	Patients (n)	Age range (yr)	Follow-up period (yr)	Mean FEV1 decline (mL/yr)
Bridevaux et al	SAPALDIA 1	I	430	18–60	11	40 ± 37
Vestbo et al	CCHS	I–II	145	59 ± 10	3	42
Anthonisen et al	LHS	II	1964	35–60	5	56
Pauwels et al	EUROSCOP	II	643	30–65	3	69
Anthonisen et al	LHS-3	II	1357	30–60	11	53
LHS Research Group	LHS-2	II	557	40–69	3	47
Jenkins et al	TORCH	II	535	40–80	3	60
Lapperre et al	GLUCOLD	II	24	45–75	3	79
Decramer et al	UPLIFT	II	1355	64 ± 9	4	49
Burge et al	ISOLDE	III	375	40–75	3	59
Jenkins et al	TORCH	III	775	40–80	3	56
Decramer et al	UPLIFT	III	1331	65 ± 8	4	38
Jenkins et al	TORCH	IV	214	40–80	3	34
Decramer et al	UPLIFT	IV	271	63 ± 8	4	23††

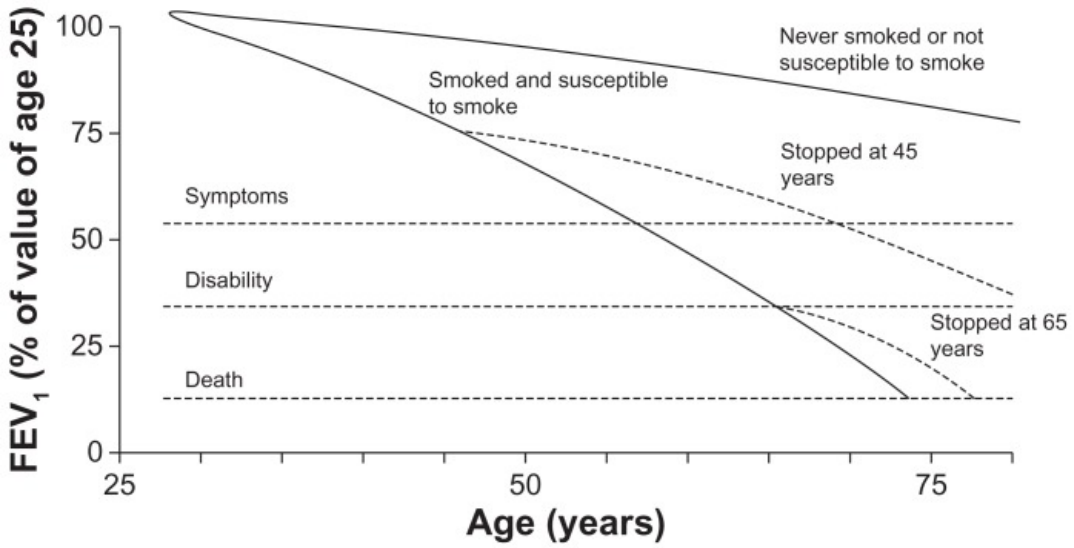
According to the evidence provided the acceleration of lung function was more so in the early stages and hence early intervention is much better than at later stages with anatomical damage.

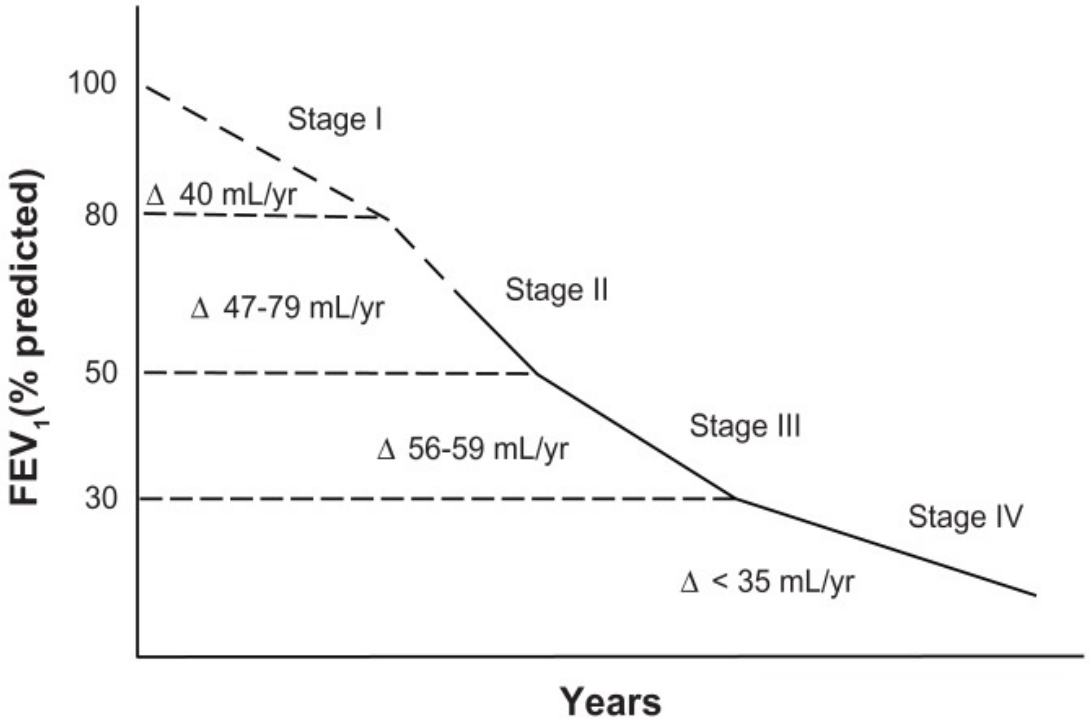
Hence, a different curve pattern in the decline of lung function was elucidated which contradicts the view of Fletcher and Peto's curve.



This trend is explained by the more loss in early stages of COPD than at later stages. This FEV1 loss can be partly compensated by the increase in total lung capacity in GOLD stage IV COPD patients. Some studies have shown that FEV1 is poorly related to symptoms and even to exacerbations. Therefore, a greater loss of lung function during the early stages of disease holds good.

Comparison of Fletcher and Peto's curve with newer envisaged Curve





MATERIALS AND METHOD

Study design:- observational study

Study period:- 6 months

Study area:- GOVT KILPAUK MEDICAL COLLEGE

Study population**:**

Males among age group18-50 years are recruited.

Study population includes both smokers and non smokers

The subjects selected for present study will be recruited from medical outpatient Department at our hospital.

SAMPLE SIZE:-

Smokers :75

Non smokers :75

INCLUSION CRITERIA:

The random sample of smokers and non smokers will be selected who fulfill the following criteria

NON SMOKERS:

Person who does not smoke tobacco

Person not dwelling in the home where their spouse or other family members are smokers of hookah,cigarette,cigar or beedi.

(In other words they were not passive smokers. A passive smoker refers to exposure to tobacco consumption products from smoking of others)

SMOKERS:

They are persons who are engaged in the inhalation and exhalation of fumes of burning tobacco in cigarettes.

By definition, cigarette smokers are the persons who inhale, exhale and burn or carry any lightened cigarette. (the person who smokes atleast 5 cigarettes per day for 10 years)

EXCLUSION CRITERIA:

The following groups of persons will not be included in the study.

1. Females
2. Known case of BA,COPD,TB,ILD
3. The person who are morbid or have full fledged picture of cor pulmonale on clinical examination.
4. The person who work in textile mills or other places where lungs are affected by dust or fumes.

METHODOLOGY

- Each person who fulfill the inclusion criteria will be included in the study.
- Clinical history to be taken. More emphasis to be made on occupational history.
- Enquiry on smoking habits. Duration and the average number of cigarettes per day.
- All the tests will be done between 10.00 to 17.00 hours to avoid possible diurnal variation.
- Each person will be allow to take rest for about two minutes before the actual test.
- The details of the test will be explain and demonstrate to each of them by myself or by operator.
- The person has to be asked to take deep inspiration from outside and then to expire as forcefully and as fast as he can inside the mouthpiece.
- Expiratory flow volume curves will be recorded by spirometer
- The value of Mid Expiratory Flow Rate will be obtained from the graph. The data of each patient will be collected in specific proforma (ANNEXURE 2) which includes patient's name, age,

sex, demographic details, presenting complaints, risk factors and all clinical data.

- All the relevant data and values are then entered in master chart in Microsoft excel format an then analyzed statiscially.

STATISTICAL ANALYSIS

Statistical Analysis

The data was collectedin the master chart obtained in the Microsoft excel format.

The collected data were analysed with IBM.SPSS statistics software 23.0 version. To describe the data descriptive statistics frequency analysis, percentage analysis was used for categorical variables and the mean and Standard deviation was used for continuous variables. To find the significant difference between the bivariate samples in Independent groups the unpaired sample t-test was used. For the multivariate analysis, the **KrusalWalli's** was used. In both the above statistical tools the probability value 0.05 is considered as significant level.

Results:

The results of test conducted among 75 participants who smokers and equal number of participants without smoking history. Age group with maximum distribution was among 41-50 years of age (N=64 ;42.7%). All participants selected were under 50 years to exclude inert conditions like IHD,Systemic hypertension with the interpretation of results. Duration of cigarette smoking was maximum at 11-20 years of smoking which more or less applies to majority of population in society.

Descriptive statistics:

Descriptive analysis among smokers have shown following details:

	N	Minimum	Maximum	Mean	Std. Deviation
CIGARETTES PER DAY	75	10.0	25.0	17.880	3.4834
DURATION	75	10.0	35.0	20.440	6.0855
PACK YEARS	75	7.5	30.0	18.125	5.9711
Valid N (listwise)	75				

The mean cigarettes smoked per day was around 18 among participants.

Mean duration was 20 years which extrapolates to the general population at large.

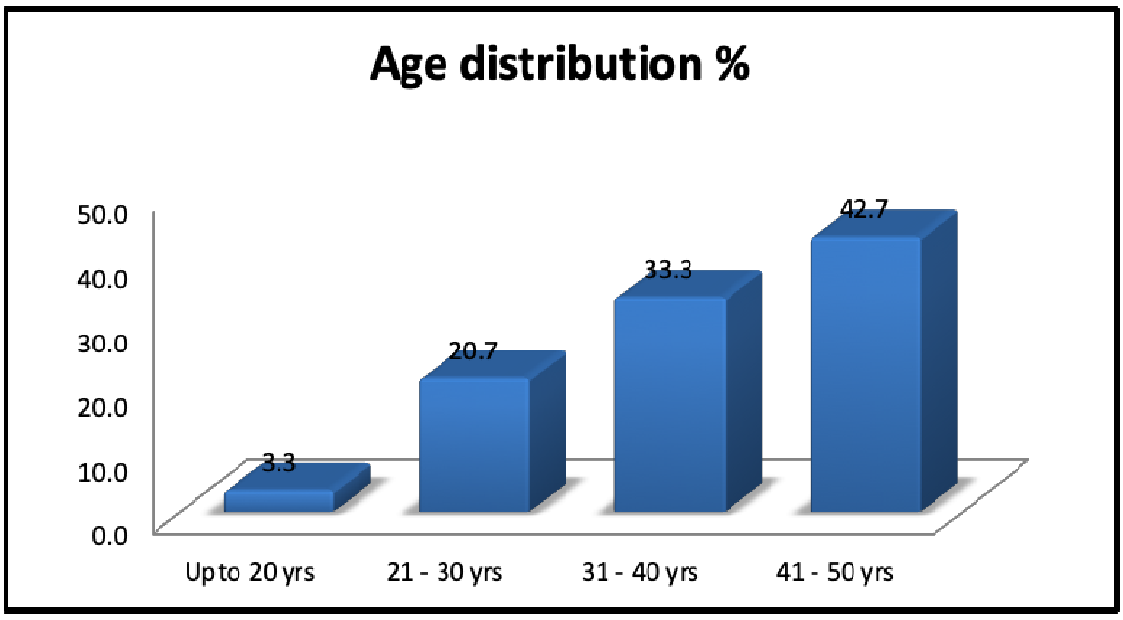
Pack years amounts to 18 which leads to susceptible population.

Frequency Table

Age distribution

	Frequency	Percent
Upto 20 yrs	5	3.3
21 - 30 yrs	31	20.7
31 - 40 yrs	50	33.3
41 - 50 yrs	64	42.7
Total	150	100.0

Among 150 participants age distribution was maximum among 41-50 years group(N=64;42.7%). This represents the larger proportion of people in the society and hence represents the larger picture among the community. Likewise, next lesser frequency is among 31-40 years of age (N=50;33.3%). Least representation is under 20 years of age (N=5;3.3%).

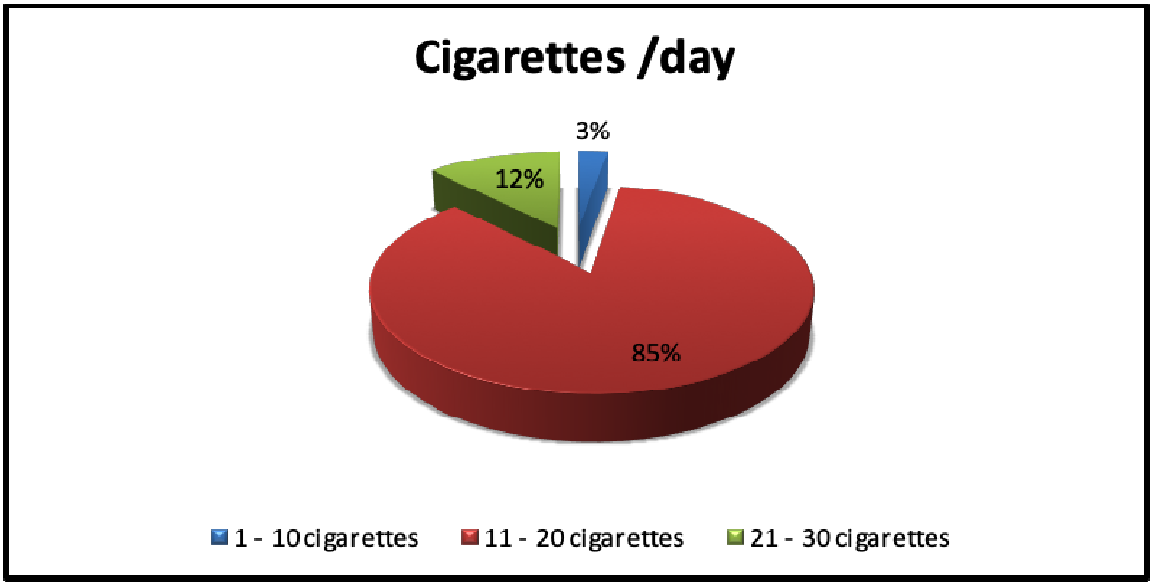


Cigarettes per day

Among smokers Number of cigarettes smoked per day:

No of cigarettes	Frequency	Percent
1 - 10	2	2.7
11 - 20	64	85.3
21 - 30	9	12.0
Total	75	100.0

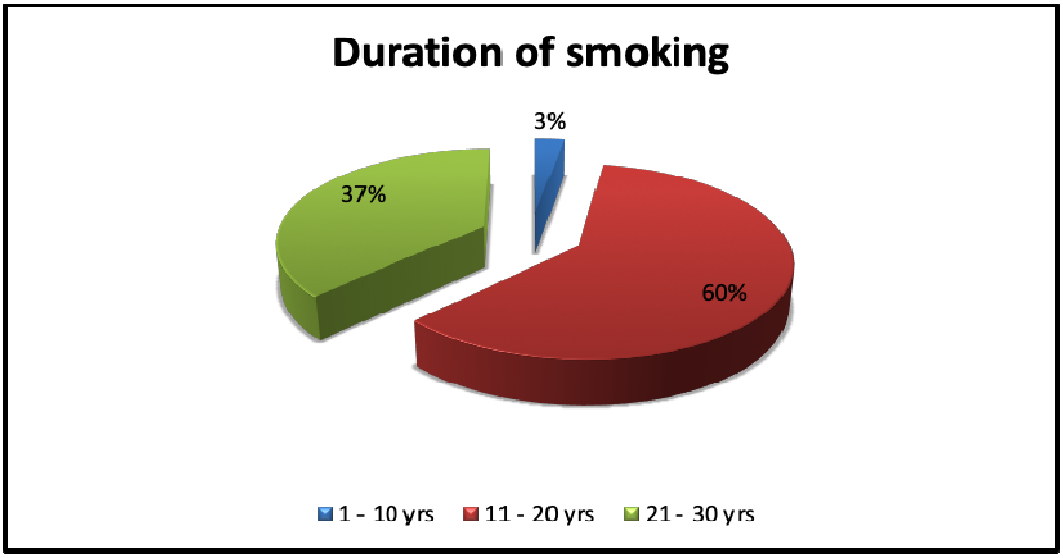
2.7 % (N=2) of participants were smoking around 1-10 cigarettes per day; majority were smoking 11 to 20 cigarettes per day (N=64;85.3%) and only 9 participants were smoking around 21-30 cigarettes (12%) which is a high burden on health.



Duration of smoking:

Maximum number of persons were smokers for 11-20 years (N=45;60%); with 37.3 percent of participants (N=28) were smokers for 21-30 years. Only 2.7% of participants are smokers for 1-10 years.

Duration of smoking	Frequency	Percent
1 - 10	2	2.7
11 - 20	45	60
21 - 30	28	37.3
Total	75	100.0

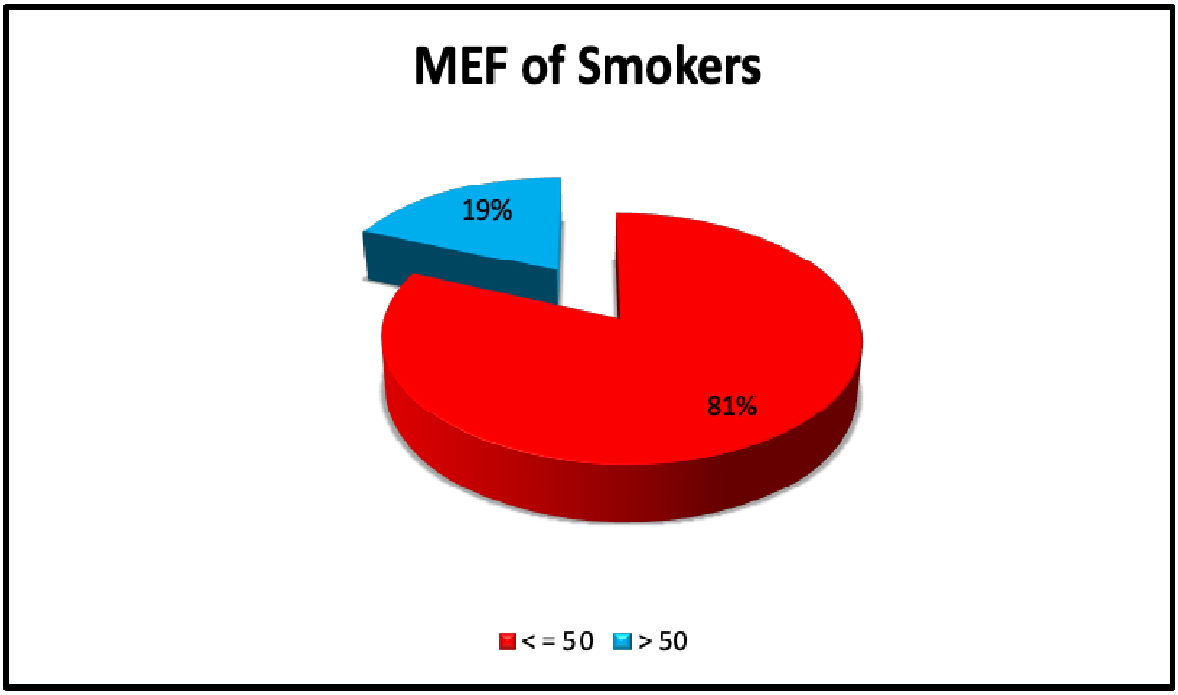


MEF 25-75%

Mid expiratory flow rate 25-75 among smokers was calculated and results were extrapolated in terms of less than or equal to 50 and people with more than 50.

Huge number of smokers had their MEF 25-75 less than 50 (N=61;81%) and a mere 14 were under 50 categories.

	Frequency	Percent
< = 50	61	81.3
> 50	14	18.7
Total	75	100.0

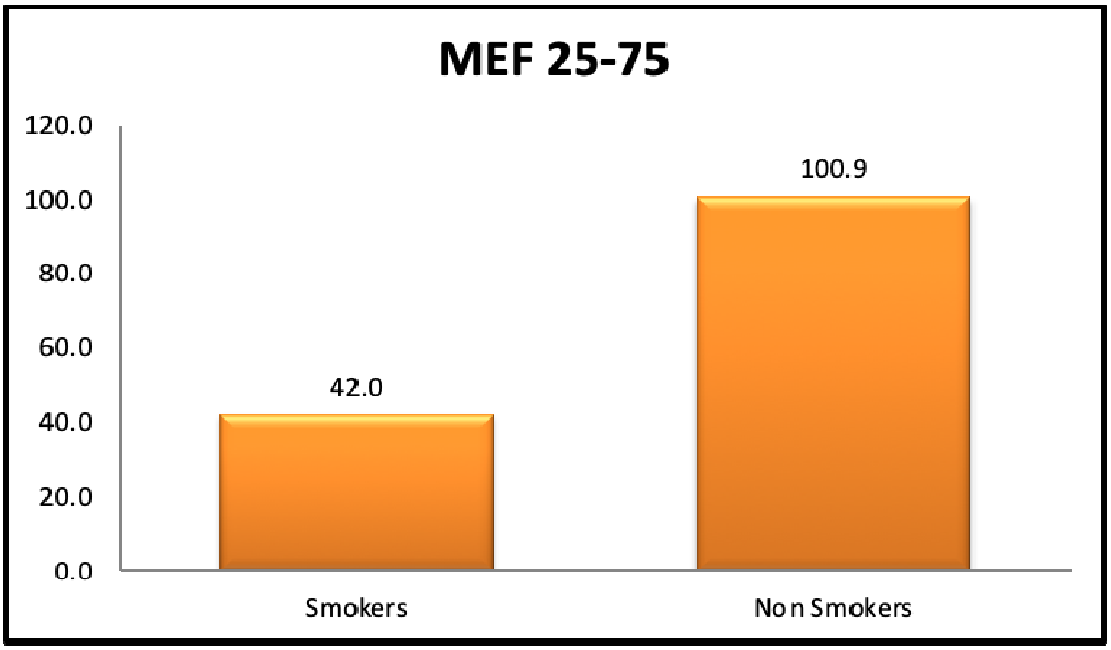


Comparison of MEF 25-75% among Smokers and Non-smokers:

		N	Mean	Std. Deviation	Std. Error Mean
MEF 25-75	Smokers	75	42.0	8.922	1.030
	Non Smokers	75	100.9	7.906	0.913

Smokers had a mean MEF 25-75 of only 42.

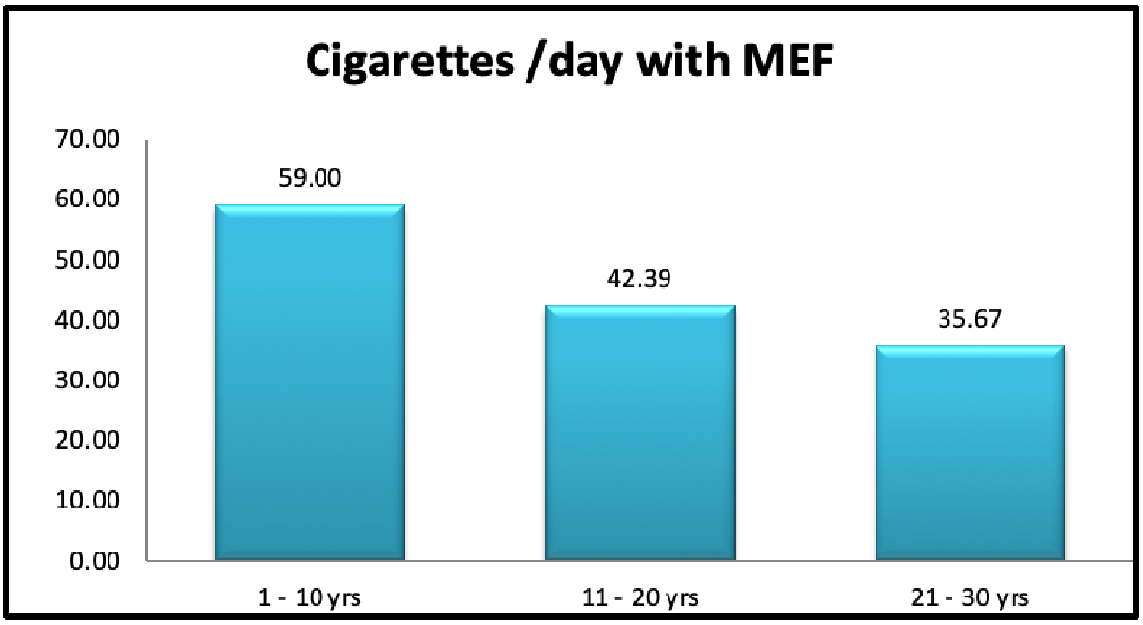
Non-Smokers as expected had little restriction with mean ranging around 100.



Description of MEF among smokers with cigarettes per day:

Cigarettes	N	Mean	Std. Deviation	Minimum	Maximum
1 - 10	2	59.00	0.000	59	59
11 - 20	64	42.39	8.664	26	60
21 - 30	9	35.67	5.148	27	43
Total	75	42.03	8.922	26	60

Among participants with smoking history MEF 25-75%; 1-10 cigarettes per day of smoking with 2 members with mean of 59 in MEF 25-75%.



With 11-20 cigarettes per day of smoking the reduction is further exaggerated to level of 42 with minimum 0f 26 to maximum of 60.

Further increase in the number of cigarettes of 21-30 per day is reflected in the MEF 25-75 reduction to mean of 35.67 with minimum of 26 to maximum of 43.

This proves that more the increase in the number of cigarettes more reduction in the MEF 25-75 and hence plays a major role in the COPD pathogenesis.

Test Statistics (a,b)

	MEF 25-75
Chi-Square	10.762
df	2
Asymp. Sig.	.005

a. Kruskal Wallis Test

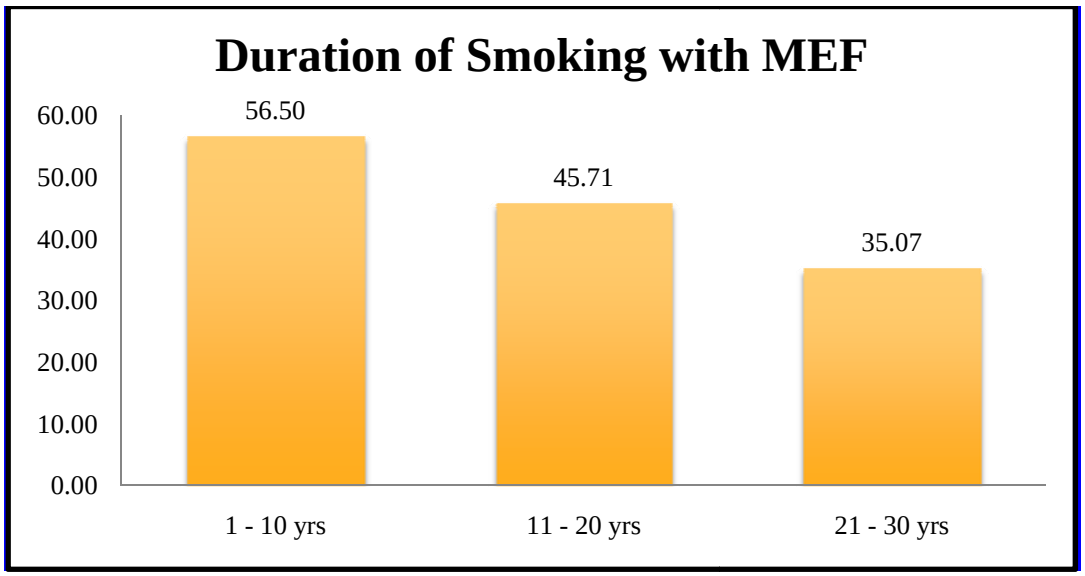
b. Grouping Variable: Cigarettes per day

Duration of smoking with MEF 25-75%

	Number	Mean	Std. Deviation	Minimum	Maximum
1 - 10 yrs	2	56.50	2.121	55	58
11 - 20 yrs	45	45.71	7.384	32	60
21 - 30 yrs	28	35.07	6.388	26	49
Total	75	42.03	8.922	26	60

People with 1-10 years of smoking MEF was around 56 which was near normal.

But participants with 11-20 years of smoking mean MEF was 45.71; has shown a drastic reduction. A further decade of increase in smoking duration reduces the MEF by further 10 to around 35. The maximum MEF attained by participants are also in decreasing showing a uniform trend in the decline in lung volumes over years of smoking.



DISCUSSION

The Mid-expiratory flow rate (MEFR) causes obstruction of airways more commonly the smaller airways. Likewise in our study, the obstruction of smaller airways is projected by a decrease in MEFR among smokers. The more alarming trend in the increase in the smoking among the adolescents 11 within communities has been projected in our study. Up to 20 years, our participants were around 3.3%; 21-30 years 20.7 % were included in our group. More participants were included 11-20 years of duration of smoking which was around 60 percent of the study group among smokers.

Next comes is 21-30 years of smoking which was around 37.3 percent.

Most of the studies conducted have a similar trend of the smoking pattern. The similar trend is due to the addiction pattern seen in the individuals among societies.

Next important pattern seen is the cigarettes per day wherein the similar fashion is seen. Here the number of cigarettes ie 11-20 per day is 85.3% is among the participants. The next group is smoking around 21-30 cigarettes per day is around 12%. The least which is 1-10 of cigarettes per day is 2.7 percent.

This creates a unique combination of an increasing number of cigarettes and the duration of cigarettes. More the duration increases the number of cigarettes. The MEFR was drastically reduced with more the duration and more the number of cigarettes smoked. According to GATS 2 the tobacco users by age group was around 12.4% in 15-24 years; 30.1% in 25-44 years; 39.9% in

45-64 years and 41.4% in 65 plus age group. This similar trend was noticed with an increase in smoking in the middle age group of people. In Tamil Nadu, the overall prevalence was around 5.2%with males around 4.3% and females 0.9 %.

The important point to note is that the smoking issues among rural and urban areas in narrowed with the rising awareness and reachability of tobacco products to nook and corner of the country. Tobacco use was around 2.5% in urban compared to 2.6% in rural areas. According to the Government data, 27 COPD is ranking 7th in Northeastern states and 4th in rest of the states, telling the penetrance of tobacco on a widespread level.

The important parameter into consideration in the evaluation of smokers is the development of the obstructive pattern noted in the smaller airways.

MEFR 25-75% was less than 50 in around 81 percent of smokers implying the nature of burden in the smaller airways in asymptomatic smokers. This alarming reduction in the MEFR among smokers that too in asymptomatic participants urges the physician to screen all patients with smoking history to undergo rigorous psychological procedures to curtail its use.

As shown in our study the number of cigarettes and duration are synonyms which explains the basis of involvement of reward centers and other addiction centers in the brain.

This was well supported in our study wherein the Non-smokers had a MEFR 25-75% mean of 100 compared to 42.0 which is a significant reduction in the MEFR in terms of diagnosis and the natural course of the disease.

The trend in Fletcher and Peto ’s curve was supported; more reduction in the flow rate with increase in the duration of smoking.

In our study, 1-10 years of smoking was accounting to a MEFR mean of 57

And a further decline in the subsequent study group among smokers.

11 – 20 years of smoking had a MEFR mean of 45.71which is a significant decline

And more than 20 years smoking amounting to a mean of 35.

This supports Fletcher and Peto’s hypothesis.

But the drastic drop in the MEFR in smokers with less duration of smoking as compared with non-smokers in our group has challenged the Fletcher and Peto’s results stating decline in pulmonary function in terms of spirometric values goes hand in hand with duration.

The proportion of reduction in more with early smokers than with chronic smokers over 20 years.

Various studies support our results wherein in the reduction of flow rates in particularly MEFR is more in early stages than in the late stages.

This urges the physician at a community level to curb the menace of smoking at the earliest.

CONCLUSION

- Mid Expiratory flow rate 25-75% is reduced in chronic smokers.
- The rate of reduction in MEFR 25-75% is earlier among asymptomatic smokers than non smokers
- This is contrary to the popular belief that longer the duration of smoking there is an increased rate of reduction of MEFR 25-75%
- The MEFR 25-75 % is normal in the non-smoker group – irrespective of the age distribution.
- The reduction in MEFR25-75% is directly proportional to the duration as well as quantum of smoking.
- Hence decreasing the quantum of smoking as well as early cessation of smoking prevents COPD.

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ANNEXURE A

PROFORMA

PROFORMA

NAME:

AGE/SEX:

ADDRESS:

OCCUPATION:

IP/OP NO:

QUESTIONNAIRE:

Kuppusamy socio economic state:

Smoker/non smoker:

Duration of smoking:

No of cigarettes per day:

Pack years:

Passive smoking:

Co morbid illnness: SHT/DM/BA/COPD/TB/ILD:

Family history of SHT/DM/BA/COPD/TB/ILD:

PULMONARY FUNCTION TEST:

MID EXPIRATORY FLOW RATE (25-75):

ANNEXURE 2

MASTER CHART

SR.NO	AGE	SMOKER	NON SMOKER	CIGARETTES PER DAY	DURATION	PACK YEARS	MEF 25-75%
1	48	YES		20	30	30	28%
2	34		YES				97%
3	39	YES		18	15	14	46%
4	48		YES				96%
5	38	YES		20	15	15	44%
6	27		YES				104%
7	35		YES				99%
8	40	YES		20	18	18	43%
9	48	YES		20	15	15	45%
10	22		YES				104%
11	42	YES		15	22	17	45%
12	39	YES		20	14	14	48%
13	24		YES				102%
14	20		YES				119%
15	40	YES		20	25	25	35%
16	25		YES				108%
17	43	YES		16	21	17	42%
18	21		YES				115%
19	31		YES				104%
20	50	YES		15	30	22	34%
21	41	YES		18	15	14	45%
22	45		YES				85%
23	50	YES		16	35	28	26%
24	21		YES				110%
25	43		YES				98%
26	48	YES		20	25	25	34%
27	45	YES		22	20	22	35%
28	30		YES				102%
29	39		YES				96%
30	49	YES		18	20	18	43%
31	44		YES				85%
32	44	YES		15	20	15	44%
33	28		YES				106%
34	30		YES				103%
35	20		YES				116%
36	44	YES		20	20	20	38%
37	39	YES		15	19	14	48%
38	31		YES				106%
39	40		YES				97%
40	48	YES		20	18	18	40%
41	43	YES		20	25	25	34%
42	25		YES				109%
43	23		YES				106%
44	50	YES		20	25	25	35%
45	33		YES				93%
46	50	YES		12	30	18	45%
47	47	YES		12	24	14	49%

48	37		YES				97%
49	25		YES				103%
50	48	YES		15	30	23	34%
51	39	YES		15	18	14	47%
52	31		YES				110%
53	49	YES		15	20	15	44%
54	26		YES				103%
55	34		YES				98%
56	18		YES				116%
57	50	YES		20	30	30	28%
58	43	YES		18	15	14	49%
59	50	YES		24	20	24	35%
60	39	YES		15	13	9.8	53%
61	23		YES				109%
62	48	YES		20	28	28	27%
63	39		YES				93%
64	38	YES		15	10	7.5	58%
65	29	YES		20	10	10	55%
66	30		YES				102%
67	41	YES		15	12	9	55%
68	50	YES		25	20	25	34%
69	42		YES				95%
70	40		YES				89%
71	50	YES		21	16	17	43%
72	36		YES				99%
73	50	YES		15	30	23	33%
74	24		YES				103%
75	49		YES				96%
76	47	YES		15	25	19	40%
77	20		YES				114%
78	49	YES		25	24	30	27%
79	32		YES				93%
80	39	YES		15	15	11	54%
81	28		YES				106%
82	45	YES		20	15	15	45%
83	33		YES				94%
84	29		YES				103%
85	49	YES		24	20	24	33%
86	41	YES		16	21	17	42%
87	42		YES				87%
88	39	YES		20	15	15	44%
89	22		YES				110%
90	49	YES		15	25	19	41%
91	34		YES				101%
92	26		YES				108%
93	48	YES		24	15	18	40%
94	50	YES		20	30	30	29%
95	46		YES				94%
96	39	YES		20	12	12	51%
97	35		YES				101%

98	47	YES		15	30	23	32%
99	49	YES		20	20	20	39%
100	47		YES				84%
101	37		YES				97%
102	29		YES				105%
103	47	YES		20	27	27	30%
104	26		YES				105%
105	43	YES		20	20	20	37%
106	23		YES				109%
107	39	YES		16	12	9.6	58%
108	42		YES				85%
109	48	YES		15	28	21	35%
110	40		YES				93%
111	45	YES		24	15	18	42%
112	25		YES				108%
113	39	YES		14	19	13	50%
114	28		YES				102%
115	38		YES				96%
116	42	YES		20	22	22	35%
117	43	YES		14	23	16	46%
118	33		YES				101%
119	34	YES		18	14	13	54%
120	39	YES		20	15	15	46%
121	27		YES				109%
122	36	YES		15	12	9	60%
123	35		YES				93%
124	38	YES		10	18	9	59%
125	49	YES		16	35	28	29%
126	43		YES				97%
127	36	YES		15	16	12	53%
128	44	YES		20	13	13	45%
129	21		YES				108%
130	50	YES		20	25	25	33%
131	35	YES		20	15	15	46%
132	32		YES				96%
133	48	YES		20	20	20	38%
134	19		YES				105%
135	41		YES				98%
136	48	YES		15	30	22	34%
137	44	YES		14	20	14	48%
138	32		YES				94%
139	38	YES		10	19	9.5	59%
140	24		YES				109%
141	37		YES				99%
142	50	YES		20	20	20	37%
143	41		YES				83%
144	27		YES				106%
145	39	YES		15	15	11	55%
146	43	YES		24	20	24	32%
147	29		YES				101%

148	38	YES		12	20	12	53%
149	36		YES				102%
150	38		YES				95%

ANNEXURE 3

PATIENT CONSENT FORM

- Study detail : **"COMPARATIVE STUDY OF MID EXPIRATORY FLOW RATE BY USING SPIROMETRY IN AYMPTOMATIC SMOKERS AND NON SMOKERS AS A MARKER OF EARLY AIRFLOW OBSTRUCTION"**

- Study centre : KILPAUK MEDICAL COLLEGE, CHENNAI
- Patients Name:
- Patients Age:
- Identification Number :
- Patient may check ( ) these boxes
- I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction.
- I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected.
- I understand that sponsor of the clinical study, others working on the sponsor's behalf, the ethical committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that may be conducted in relation to it, even if I withdraw from the study I agree to this access. However, I understand that my identity will not be revealed in any

information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study.

- I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well-being or any unexpected or unusual symptoms.
- I hereby consent to participate in this study.
- I hereby give permission to undergo complete clinical examination and diagnostic tests including hematological, biochemical, radiological tests.

Signature/thumb impression:

Patients Name and Address: place

date

Signature of investigator:

- Study investigator's Name: place date

சுயஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு:

இடம்: பொது மருத்துவத்துவ துரை

அரசு கீழ்பாக்கம் மருத்துவ கல்லூரி மருத்துவமனை

சென்னை

பங்குபெறுபவரின் பெயர் :

பங்குபெறுபவரின் வயது :

பங்குபெறுபவரின் எண் :

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது.நான் இவ்வாய்வில் தன்னிச்சையாக பங்கேற்கிறேன்.எந்த காரணத்தினாலோ எந்த சட்டசிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகிக்கொள்ளல்லாம் என்றும் அறிந்து கொண்டேன்.

இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்து மேலும் ஆய்வு மேற்கொள்ளும்போதும் இந்த ஆய்வில்பங்கு பெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். இந்த ஆய்வின் மூலம் கிடைக்கும் தகவலையோ, முடிவையோ பயன்படுத்திக்கொள்ள மறுக்க மாட்டேன்.

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்றும் உறுதியளிக்கிறேன்.

பங்கேற்பவரின் கையொப்பம் ஆய்வாளரின் கையொப்பம்

இடம் :

தேதி :